UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 5 CASES LISTED IN EXHIBIT A TO PLAINTIFFS' MOTION**	

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN TESTIMONY OF MARSHALL D. SHOEMAKER, M.D.

Dr. Shoemaker is a gynecologist with board certification in Obstetrics and Gynecology. *See* Marshall Shoemaker, M.D., Curriculum Vitae ("Shoemaker CV") [Dkt. 4328-8]; Expert Report of Marshall Shoemaker, M.D. Gynemesh PS, Prolift, Prolift+M, and Prosima ("Prolift Report") [Dkt. 4328-2]; Expert Report of Marshall Shoemaker, M.D. re TVT, TVT-O, TVT Abbrevo, and TVT Exact ("TVT Report") [Dkt. 4328-3]. Under Rule 702, he is without question an expert in the fields of pelvic medicine generally and in the surgical treatment of pelvic organ prolapse and stress urinary incontinence specifically.

Dr. Shoemaker prepared two general reports for Wave 5—one addresses the pelvic organ prolapse medical devices manufactured by Ethicon, Inc. (Gynemesh PS, Prolift, Prolift+M, and Prosima); the other addresses the stress urinary incontinence medical devices manufactured by Ethicon, Inc. (TVT, TVT-O, TVT Abbrevo, and TVT Exact).

Plaintiffs do not challenge the overwhelming majority of Dr. Shoemaker's general opinions. Rather, Plaintiffs only seek to limit Dr. Shoemaker's testimony on two points: (1) his opinions about the devices' IFUs and Surgeon's Resource Monograph, and (2) his opinions

about the physical properties of Ethicon's Prolene mesh as it interacts with the human body after implantation. Plaintiffs assert a qualifications challenge and a methodology challenge to each of these two opinions. Neither category of challenge is availing.

First, Dr. Shoemaker is qualified to offer his IFU/Monograph opinions. Dr. Shoemaker opines that the IFUs and Monograph adequately apprise surgeons of the risks associated with the subject devices. To arrive at this opinion, Dr. Shoemaker relied on his clinical experience with the devices and conducted a review of the medical literature to determine the risks associated with the devices. Then, he compared those risks to the warnings contained in the IFUs and Monograph and opined that those risks are adequately addressed in the IFUs and Monograph. As a board certified surgeon in obstetrics and gynecology who has performed literally thousands of prolapse and SUI surgeries using the subject devices, Dr. Shoemaker is imminently qualified to offer this opinion. To the extent that Plaintiffs argue that Dr. Shoemaker needs some additional qualifications to opine about what should or should not be included in a medical device IFU, Plaintiffs misapprehend the nature of Dr. Shoemaker's testimony. He has not and will not opine about what should or should not be included in the IFUs; rather, his opinion is that the risks associated with these devices are adequately identified in the IFUs.

Second, Dr. Shoemaker's methodology in arriving at his IFU/Monograph opinions is reliable. Dr. Shoemaker relied on both his clinical experience and his medical literature review. Plaintiffs argue that there is medical literature that is contrary to Dr. Shoemaker's opinions, that he failed to give sufficient weight, and that his medical review failed to identify certain articles that were unrelated to transvaginal mesh. Plaintiffs' arguments all go to the weight to be given to Dr. Shoemaker's opinions by the trier of fact—not their admissibility. Thus, these challenges should be reserved for cross-examination.

Third, Dr. Shoemaker is qualified to opine about how Prolene mesh interacts with the human body *in vivo*. Plaintiffs argue that Dr. Shoemaker cannot offer "design" opinions because he has not been involved in the process of designing any transvaginal mesh products. Plaintiffs' efforts to shoe horn Dr. Shoemaker's physical properties opinions as "design process" opinions as being relevant to a design defect claim miss the mark entirely. Dr. Shoemaker is not opining about the process by which Ethicon developed and designed these devices. His opinions are limited to how the polypropylene mesh in these devices (i.e., the physical properties of the mesh) interacts with the human body. As a board certified surgeon who has implanted thousands of these devices in women and subsequently followed his patients post-implant, Dr. Shoemaker is more than qualified to discuss how the products interact with the human body.

Finally, Dr. Shoemaker's methodology in arriving at his opinions regarding how the physical properties of Prolene interact with the human body is based on a reliable methodology. Dr. Shoemaker relied on his clinical experience, his review of the scientific peer-reviewed medical literature, and the same type of methodology found in this literature. Plaintiffs' attacks on his methodology in fact go to the weight to be given, not the admissibility of, his opinions.

For these reasons, Plaintiffs' motion to limit Dr. Shoemaker's testimony should be denied.

LEGAL ARGUMENT AND AUTHORITIES

Plaintiffs ostensibly make only two challenges to Dr. Shoemaker, arguing that he is unqualified to offer opinions about the IFUs and that he is unqualified to offer design opinions. Upon review, Plaintiffs' Brief [Dkt. 4329] reads like a cross-examination rather than a *Daubert* motion. Peppered throughout their two overarching contentions, Plaintiffs also assert various methodology challenges. Ethicon addresses the enumerated qualification challenges first. Then

Ethicon will address Plaintiffs' random methodology contentions contained within the qualifications challenges.

I. Dr. Shoemaker Is Qualified to Opine on the IFUs and Surgeon's Resource Monograph.

Dr. Shoemaker opines that Ethicon's IFUs, Surgeon's Resource Monograph, and the common knowledge of pelvic floor surgeons apprise surgeons of the risks associated with the various Ethicon products. To arrive at this opinion, Dr. Shoemaker relied on his decades of experience implanting these devices and his extensive review of the medical literature. Throughout the body of his reports, Dr. Shoemaker identifies the risks associated with non-mesh prolapse and SUI surgery. Likewise, he identifies the risks associated with mesh prolapse and SUI surgery. He compares the non-mesh risks to the mesh risks and identifies which risks are unique to mesh surgery. Then, Dr. Shoemaker compares those risks to the language of the IFUs and Monograph. Ultimately, he concludes that the Ethicon adequately warned the intended users of these products—i.e., surgeons like Dr. Shoemaker—of the risks unique to these devices. Dr. Shoemaker's qualifications to engage in this type of analysis are his education, training, and decades of experience in the field of pelvic reconstruction surgery and SUI repair.

Plaintiffs argue that Dr. Shoemaker is unqualified to offer this opinion because he lacks training and experience with the FDA 510(k) approval process and he has not been involved in the creation of a device IFU. *See* Pls.' Br. [Dkt. 4329] at 4. Additionally, Plaintiffs contend that Dr. Shoemaker's clinical experience using the subject products and his review of the medical literature does not qualify him to offer any opinions about the IFUs for these products. *See id.* at 4-5. Plaintiffs' arguments are contrary to this Court's holdings.

First, Plaintiffs' argument that Dr. Shoemaker's opinions are inadmissible because he did not rely on FDA regulations rests entirely on the supposition that expertise in FDA regulations

related to requirements for IFUs is mandatory for these opinions. Yet, the job of an expert witness is to identify the pertinent facts of the case and opine about their relevance related to the factual allegations of the Master Complaint. *See* Fed. R. Evid. 702 (a) ("help the trier of fact to understand the evidence or to determine a fact in issue"), (b) ("the testimony is based on sufficient facts or data"). It is not the expert's job to provide the court with the law. This Court, in fact, has excluded testimony which not only stated facts but also expressed a legal conclusion. *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2014 WL 186872, at *20 (S.D. W. Va. 2014) (citing *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)). The key question here is whether Dr. Shoemaker's testimony is based on his scientific, technical, or other specialized knowledge, skill, experience, training, and professional education, thereby enabling him to help the trier of fact to understand the evidence or to determine a fact in issue, and not whether he himself could articulate or opine about the governing legal standard. If he had attempted to do that, his testimony would have been excluded.

Dr. Shoemaker's IFU opinions and qualifications and his IFU opinions are similar to those previously found to be admissible by this Court. In *Trevino v. Boston Scientific Corp.*, 2:13-CV-01617, 2016 WL 2939521, at *13-14 (S.D. W. Va. May 19, 2016), the defendant sought to exclude the warnings testimony of plaintiff's urogynecologist Bobby L. Shull, M.D. There, the defendant argued that Dr. Shull was not qualified to opine on the adequacy of the IFU because Dr. Shull "is not an expert in the regulations or standards that govern [IFUs]; he has never advised a company on a[n IFU]; he is unfamiliar with the industry process governing [IFUs]; and he has not even performed a literature search relating to DFUs." *Id.* at * 13. The plaintiff noted that Dr. Shull had not been designated to offer any opinions regarding the manner by which the defendant developed the IFU or the regulatory requirements applicable to IFUs. *Id.* Instead, Dr.

Shull was only offered "to opine on the completeness and accuracy of the [product's] warnings from a clinical perspective." *Id.* at *40-41. This Court held that Dr. Shull's testimony along these lines would be admissible:

> Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that that the Uphold DFU did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison. *See, e.g., Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (finding Dr. Blaivas, a urologist, qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's DFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are 'fully qualified to opine on the medical facts and science regarding the risks and benefits of [drugs] ... and to compare that knowledge with what was provided in the text of labeling and warnings ...." (quoting *In re Diet Drugs Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at 11 (E.D. Pa. June 20,2000))). I also find that Dr. Shull's forty years of experience, along with his evaluation of medical literature forms a reliable basis for this testimony. *Kumho Tire Co.*, 526 U.S. at 156 (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience").

Id. Just like Dr. Shull, Dr. Shoemaker is relying on his years of clinical experience and his review of the medical literature to identify the risks associated with the devices and opines that the respective IFUs and Monograph did warn physicians of the risks.

As discussed above, the legal principle that controls here is that a device manufacturer's duty to warn of adverse events is limited to events unique to the device. It does not include a duty to warn of risks commonly known to the surgeons who use the device. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j (seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users."); *see also* RESTATEMENT (SECOND) OF THE LAW

OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (Va. 2009) (adopting "sophisticated user" defense in §388).

This limitation on the duty to warn is recognized in medical device cases as well. There is no duty to warn of risks that are commonly known by implanting surgeons. *See Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community"). In fact, the FDA regulations recognize that risk-related information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added).

Here, the devices' IFUs restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. *See, e.g.*, Ex. A, Prolift IFU (ETH.MESH.02341459) at 6 ("Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems."); Ex. B, Prolift+M IFU (ETH.MESH.01595615) at 2 ("Physicians should have experience in management of complications resulting from procedures using surgical mesh. . . . Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT+M™ Systems."); Ex. C, TVT-O IFU at 1 (ETH.MESH.00860240) ("This package insert is designed to provide instruction for use of the GYNECARE TVT* Obturator System . . . . It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence

and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device.").

Again, the important question with respect to Plaintiffs' failure to warn claim is: what "hazards" and are "commonly known" to surgeons familiar with pelvic surgery, including surgery to address pelvic organ prolapse and SUI? That is precisely the opinion reached by Dr. Shoemaker. He reviewed the risks associated with non-mesh surgical repair. *See* Prolift Report [Dkt. 4328-2] at 5-10; TVT Report [Dkt. 4328-3] at 5-8. Dr. Shoemaker then examined the risks associated with mesh surgical repair. *See* Prolift Report [Dkt. 4328-2] at 10-33; TVT Report [Dkt. 4328-3] at 8-24. And he ultimately concludes that the risks specific to the devices were discussed in the IFU and Monograph. *See* Prolift Report [Dkt. 4328-2] at 33-37; TVT Report [Dkt. 4328-3] at 28-31. Dr. Shoemaker's scientific, technical, or other specialized knowledge, skill, experience, training, and professional education, enable him to help the trier of fact to understand the evidence or to determine the facts related to this issue.

Ethicon is mindful of the Court's Wave 1 rulings that experts without additional regulatory expertise on product labeling and compliance cannot testify "about what an IFU should or should not include." *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4557036, at *3. But that is not what Dr. Shoemaker is doing here. He will not offer opinions about what should or should not be included in an IFU. Rather, through his own experience and his examination of the medical literature, he (1) identifies the risks associated with non-mesh pelvic floor surgery and SUI surgery, (2) identifies the risks associated with mesh pelvic floor surgery and SUI surgery, (3) compares the non-mesh risks to the mesh risks to determine which, if any, are unique to the mesh surgeries, and (4) offers his opinion as to whether the IFUs and Monograph warned physicians of the risks unique to the mesh surgeries.

Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Shoemaker's conclusion can be addressed on cross-examination. *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 532 (S.D. W. Va. 2014).

II. Dr. Shoemaker Employed a Reliable Methodology in Arriving at His IFU Opinions

Strewn amongst Plaintiffs' qualifications challenge, Plaintiffs appear to assert four challenges to Dr. Shoemaker's methodology. Plaintiffs contend that his methodology is unreliable because (1) there is medical literature contrary to Dr. Shoemaker's opinions, (2) there is medical literature that Dr. Shoemaker did not include in his report, (3) Dr. Shoemaker alleged misrepresented the holdings of "multiple studies," and (4) Dr. Shoemaker relied on his clinical experience.

A. The Existence of Contrary Medical Literature Does Not Render an Expert's Opinion Unreliable

Plaintiffs argue that Dr. Shoemaker's IFU opinions are unreliable because there is medical literature that is purportedly contrary to his opinions. Specifically, Plaintiffs argue that there is "[c]onflicting evidence and scientific viewpoints" on the issue of "mesh shrinkage." *See* Pls.' Br. at 5. They also argue that Dr. Shoemaker "chose to rely on studies that he essentially 'cherry-picked' to support his opinions." *Id.* at 9. Plaintiffs cite to only one study that purportedly contained contradictory information and that Dr. Shoemaker did not consider reliable: "Mesh Related and Intraoperative Complications of Pelvic Organ Prolapse Repair." *See* Pls.' Br. at 8-9.

What Plaintiffs do not say, however, is that they specifically asked Dr. Shoemaker about this article in his deposition and he explained his basis for disagreeing with the study:

Q. So these authors are describing mesh shrinkage as one of the most frequent complications associated with mesh usage for POP; correct?

A. That's what this sentence states, yes.

Q. Do you disagree based upon your review of the literature that it's one of the most common complications?

A. I have not seen that as one of the most common. In fact, it looks like it says here .3 percent or it's 1 percent. I'm trying to read what it says. It's a low number, it looks like. Out of 677 patients, it looks like it's a low number.

…

Q. Now, this paper is in your reliance list. But that information and the description of mesh shrinkage as being one of the most serious complications is nowhere in your expert report, is it?

A. Correct, correct. Because --

…

A. Let me explain that. It's talking about five cases in this situation. And I'm not sure how you get urethral obstruction with a mesh case that was put in correctly. And also it talks about the fixation arms. I'm not sure how this was placed that it would cause this kind of situation. Maybe if it was not placed tension free, maybe that caused some of the -- when it scarred, it made the contraction worse -- the scarring of the vagina worse and caused the pain. Because I don't know how you get a urethral obstruction from a vaginal mesh. I just don't see how that could happen, unless they put it in the urethra incorrectly. There's no way it could affect the urethra, in my opinion. In fact, the mesh shouldn't be placed that far. It should stop at the urethrovesical junction, so there shouldn't be any mesh near the urethra, unless it was from a sling. But it doesn't mention that.

Shoemaker 7/21/17 Depo. [Dkt. 4328-4] 150:16-151:3, 152:1-152:24.

While Plaintiffs are correct on the limited point that an expert must take into account and consider contrary evidence, Plaintiffs fail to adduce any evidence or plausible argument that Dr.

Shoemaker failed to consider this article. It is cited in his reliance list as an article that he reviewed in forming his opinions, and at his deposition he explained his scientific bases for disagreeing with the conclusion of this article. The fact that Plaintiffs believe Dr. Shoemaker should give the article greater weight than he does goes to the weight of his testimony, not its admissibility.

B. An Expert Need Not List Every Piece of Literature for His Methodology to Be Reliable

Plaintiffs espouse the untenable position that an expert's methodology cannot be deemed reliable unless the expert lists in his report every article, paper, and publication that exists in relation to the subject matter. Specifically, Plaintiffs argue that Dr. Shoemaker did not identify a study involving hernia mesh (not transvaginal mesh) and that his failure to do so renders his IFU opinions unreliable. *See* Pls.' Br. [Dkt. 4329] at 6-8. Plaintiffs cite no case law or other authority for this novel legal proposition; this absence of citation is likely due to the fact that Plaintiffs' argument is contrary to the law and to this Court's prior holdings.

The Court rejected a similar argument in *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521 (S.D. W. Va. May 19, 2016). The plaintiff in that case challenged the competence of defense expert Stephen Badylak, M.D., to testify about the safety and efficacy of polypropylene mesh devices on the basis that Dr. Badylak had "'admitted that he ha[d] not performed a 'comprehensive review' of the literature related to [the defendant's] devices." *Id.* at *40. The Court, however, noted that Dr. Badylak's report demonstrated that he "reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices," and that "[i]f there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Id.*; *see also Bethune v. Boston Sc. Corp.*, 2016 WL

2983697, at *4 (S.D. W. Va. May 20, 2016) ("[t]o the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis's opinions, not their admissibility"; "[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions").

Plaintiffs' arguments here against Dr. Shoemaker are even less tenable. Dr. Shoemaker reviewed more than 900 articles in reaching his opinions. Plaintiffs challenge him with a single article—an article that is not about transvaginal mesh, let alone the devices at issue in this litigation. Neither the law nor the rules of evidence or civil procedure require an expert witness to review each and every study, article, and paper published on a given topic or to explain in his report why he has elected not to rely upon a certain study, article, or paper. Plaintiffs may question Dr. Shoemaker about the documents upon which he relied and his reasons for not relying on others. But this is a question for cross-examination, not for the exclusion of his opinions under *Daubert*.

C. Plaintiffs' Claim that Dr. Shoemaker Misrepresented the Studies Relied Upon Are Unfounded

Plaintiffs make the unsupported contention that Dr. Shoemaker's statements about "multiple studies" cited in his reports "differ from what the actual studies report." Pls.' Br. [Dkt. 4329] at 10. Plaintiffs do not identify these purported "studies." Instead, they materially misquote a single statement of Dr. Shoemaker in his Prolift Report about one particular article.

To this end Plaintiffs contend that Dr. Shoemaker cited the 2016 Cochrane Review for the proposition that "the use of a permanent polypropylene mesh demonstrates lower rates of … prolapse on examination in contrast to native tissue repair." Pls.' Br. [Dkt. 4629] at 10. Dr. Shoemaker actually wrote this: "[T]he use of permanent polypropylene mesh demonstrates lower rates of awareness of prolapse, reoperation for prolapse, and prolapse on examination in

contrast to native tissue repair." Prolift Report [Dkt. 4328-2] at 24 (differences between Plaintiff's quotation and Dr. Shoemaker's report underlined).

For its part, the 2016 Cochrane review states exactly what Dr. Shoemaker wrote in his Prolift Report (not Plaintiffs' altered quotation): "[P]ermanent mesh is associated with lower rates of awareness of prolapse, repeat surgery for prolapse, and prolapse on examination that native tissue repair." *See* Ex. D, Excerpts from Maher, Christopher, et al., Transvaginal Mesh or Grafts Compared with Native Tissue Repair for Vaginal prolapse, Cochrane Database of Systematic Reviews (2016) at 29.

Dr. Shoemaker cited the 2016 Cochrane Review for one of the very specific findings that it made. Plaintiffs' argument that the 2016 Cochrane Report somehow differed from Dr. Shoemaker's statement in his report is entirely unsustainable.

D. An Expert Is Entitled to Rely on His Clinical Experience in Combination with a Literature Review

Plaintiffs erroneously contend throughout their brief that an expert cannot rely on his clinical experience to form his opinions. *See* Pls.' Br. [Dkt. 4329] at 5, 8. The Court has repeatedly held that an expert can offer IFU-opinions of the type advanced by Dr. Shoemaker where the expert relies on his clinical experience and a medical literature review. *See, e.g., Trevino*, 2016 WL 2939521, at *13-14. Plaintiffs do not address, much less attempt to distinguish, these prior rulings of the Court, and their contention should be rejected yet again.

III. Dr. Shoemaker Is Qualified to Discuss the Design Properties of the Subject Products

A. Dr. Shoemaker Is Not Offering Any Design Process Opinions

Plaintiffs' attack on Dr. Shoemaker's "design" opinions is similarly unsustainable and is the latest example of what the Court deemed is a "plague" of "confusion about what constitutes a design opinion." *In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, Mem. Op. & Order

(*Daubert* Motion re: Melvin Anhalt, M.D.), MDL No. 2327, 2016 WL 4493585, at *3 (S.D. W. Va. Aug. 25, 2016). Plaintiffs contend Dr. Shoemaker cannot offer "design" opinions because he does not have a background in "designing mesh devices and has limited knowledge of the design process." Pls.' Br. [Dkt. 4329] at 12. It is clear from the context of the challenge that Plaintiffs are seeking to exclude all opinion testimony from Dr. Shoemaker about the products' design (i.e., the physical properties of the mesh) because of his personal lack of familiarity with the process by which Ethicon went about designing the devices. *See* Pls.' Br. [Dkt. 4329] at 12-16. For example, Plaintiffs cite testimony that Dr. Shoemaker was not involved in the design of any of the Ethicon devices and that he has limited knowledge about the design process actually employed for the subject devices. *See id.*

Dr. Shoemaker is not offering any such opinions about the design process. *See generally* Prolift Report [Dkt. 4328-2]; TVT Report [Dkt. 4328-3]. Rather, Dr. Shoemaker's opinions relate to the physical properties of the devices themselves—the finished product, not the process. *See* Prolift Report [Dkt. 4328-2] at 11-12 (Gynemesh PS), 16-17 (Prolift), 27-28 (Prolift+M), 30-31 (Prosima), 37-40 (responding to Plaintiffs' experts' design defect theories); TVT Report [Dkt. 4328-3] at 8-9 (Prolene generally), 9-10 (TVT and TVT-O), 14-15 (TVT Abbrevo), 16 (TVT Exact), 24-28 (responding to Plaintiffs' experts' design defect theories).

This conflation of the term "design" is now a standard practice for Plaintiffs in this MDL. They persist in this manner despite the Court providing unambiguous "clarification" and rejection of Plaintiffs' contentions about this issue:

> At first glance, it seems the plaintiffs want to prevent Dr. Anhalt from providing any opinions that even mention the word "design." But the mere utterance of a single word is not an incantation that transforms an opinion about one thing into something else.
>
> A close, contextual reading of the transvaginal mesh cases where this issue has been raised before reveals the heart of the plaintiffs'

> objections. In this motion—and several others—the plaintiffs argue that the expert at issue lacks the particularized skill, knowledge, experience, education, or training that is necessary to provide opinions about the process of designing a product. Opinions of this sort include, for example, opinions about pre-marketing product testing and product development. But upon review, I find Dr. Anhalt has not expressed any opinions about the process of designing a product.

In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig., Mem. Op. & Order (*Daubert* Motion re: Melvin Anhalt, M.D.), 2016 WL 4493585, at *3 (S.D. W. Va. Aug. 25, 2016).

Like Dr. Anhalt, Dr. Shoemaker does not opine about the design process employed by Ethicon in developing the subject devices. *See generally* Prolift Report [Dkt. 4328-2]; TVT Report [Dkt. 4328-3]. Plaintiffs' arguments that Dr. Shoemaker's "design" opinions should be excluded because he lacks the necessary qualifications to discuss the design process are wholly misplaced, and the Court should deny Plaintiffs' Motion.

B. Dr. Shoemaker Is Imminently Qualified to Offer His Opinions About the Physical Properties of the Mesh and Its Interaction with the Human Body

Those opinions of Dr. Shoemaker that Plaintiffs mischaracterize as "design" opinions are his opinions about the physical properties of the mesh and how those properties operate *in vivo*. For example, Dr. Shoemaker opines that the "clinical data" demonstrates that Prolene pelvic mesh is biocompatible, has a minimal inflammatory response, and allows for adequate tissue growth. Prolift Report [Dkt. 4328-2] at 37. Likewise, he found that the data shows that Prolene is not associated with a significantly increased risk of infection as compared to vaginal surgery in general. *Id.* Also, he opines that there is no data to suggest that Prolene is cytotoxic or causes adverse inflammatory responses, sarcoma, or cancer. *Id.* In support of these opinions, Dr. Shoemaker discusses the medical literature and his own clinical experience with the products. *See id.*

Plaintiffs challenge Dr. Shoemaker's qualifications to opine on the physical properties of the devices, erroneously contending that expert testimony cannot be based on clinical experience. *See* Pls.' Br. [Dkt. 4329] at 17-18. This is directly contrary to this Court's prior holdings.

Repeatedly, this Court has held that surgeons who have extensive experience implanting these devices are qualified to opine regarding how the mesh interacts with the human body.

> Dr. Anhalt has . . . performed or participated in over 2,000 surgeries using TVT or related mesh. He is a board-certified urologist and clinical instructor who has trained surgeons on mesh procedures. This extensive clinical experience, combined with a review of peer-reviewed literature, qualifies Dr. Anhalt to opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products. The plaintiffs' Motion is DENIED on this point.

See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig., 2016 WL 4493585, at *3.

> The plaintiffs seek exclusion of Dr. Bales's testimony about whether or not clinical data and evidence indicate that mesh degrades, is cytotoxic, is biocompatible, or causes an inflammatory response. . . . The lack of engineering expertise does not render Dr. Bales unqualified to offer these opinions, particularly because he intends to opine only on the clinical aspects of these characteristics. Dr. Bales has performed thousands of pelvic mesh procedures and treated patients experiencing complications. … This extensive clinical experience, combined with his review of peer-reviewed literature, qualifies Dr. Bale to opine on mesh's reaction to and effect on the human body. The plaintiffs' Motion on this matter is DENIED.

In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., Mem. Op. & Order (*Daubert* Mot. re: Gregory T. Bales, M.D.), MDL No. 2327, 2016 WL 4493660, at *3 (S.D. W. Va. Aug. 25, 2016)

Similarly, Dr. Shoemaker's opinions about the properties of the mesh come from his decades of experience implanting thousands of the subject devices, *see* Prolift Report [Dkt. 4328-2] at 2-3; TVT report [Dkt. 4328-3] at 2-3. as well as his extensive review of the medical literature. The Court has repeatedly found the opinion testimony of gynecologists with similar backgrounds to be admissible.

IV. Dr. Shoemaker's Methodology Used to Arrive at His Opinions About the Physical Properties of the Devises Is Reliable.

A. Plaintiffs Identify Nothing "Inappropriate" About Dr. Shoemaker's Literature Review.

Plaintiffs contend that Dr. Shoemaker's literature review was not "appropriate." Pls.' Br. [Dkt. 4329] at 13. As an initial matter, Plaintiffs appear to agree that a literature review can serve as a reliable method to arrive at an opinion regarding how Prolene interacts with the human body. *See id.* at 13. In fact, this Court has previously found a literature review to be a reliable methodology:

> [T]he plaintiffs challenge the reliability of Dr. Fleischmann's opinions that degradation, shrinkage, and contraction do not occur, or do not occur in any clinically significant manner. Dr. Fleishmann's opinions are based on her review of the medical literature, which she discusses in detail in her expert report, and her corroborating clinical experience. Dr. Fleischmann appears to be relying primarily on her review of the relevant literature. The plaintiffs claim she "ignored" contrary literature, yet Ethicon explains why the allegedly contrary literature was not relevant or relied upon by Dr. Fleischmann. The plaintiffs' concerns about Dr. Fleischmann's literature review are better suited for cross-examination. In this instance, I find sufficient indicia of reliability for Dr. Fleischmann's opinions on the material properties of mesh. The plaintiffs' Motion is DENIED on this matter.

In re: Ethicon, Inc. (*Daubert* Motion re: Nicole Fleischmann), MDL No. 2327, 2016 WL 4547049, at *3 (S.D. W. Va. Aug. 31, 2016).

It is unclear what Plaintiffs contend is "inappropriate" about Dr. Shoemaker's literature review. Only two points can be gleaned from their Brief: (1) they object to Dr. Shoemaker citing studies that report on outcomes for a time period of 24 months or less, *see* Pls.' Br. [Dkt. 4329] at 14, and (2) they object to his citing four "abstracts" as opposed to the articles, *see id.* Neither argument is availing.

1. Dr. Shoemaker's Reliance on Articles Reporting on Outcomes of Less than 24 Months Goes to Weight, Not Admissibility

Plaintiffs' argument that all studies with less than a 24 month follow-up period are unreliable is an invented criterion that has no basis in the law. Among the literally hundreds of articles reviewing transvaginal mesh, two authors have suggested that 24 months should be the minimal postoperative follow-up period. This 24-month theory is not a recognized standard among practitioners or researchers. *See generally* Reliance List [Dkt. 4328-6] (Khandwala – study in 2013 reporting on one-year outcome, Quemener – study in 2014 reporting on median follow-up of 20 months).

Second, while some of the studies relied upon by Dr. Shoemaker report on outcomes at less than 24-months, many others report on outcomes well beyond Plaintiffs' arbitrary 24-month window. *See generally* Reliance List [Dkt. 4328-6] (Angioli – 5 year results, Groutz – 10 year outcome, Laurikinen – 5 year results, Liapis 5- and 7-year follow-up, Nilsson – 5 year data, Nilsson – 11 year data, Sertait – 10 year outcome, etc.).

The fact that Dr. Shoemaker disagrees with Plaintiffs' self-invented 24-month criteria and/or that he relies on some studies that evaluate outcomes at less than 24 months in conjunction with studies that evaluate outcomes beyond 24 months goes to the weight, not admissibility, of Dr. Shoemaker's opinions.

2. Dr. Shoemaker's Reliance on Four Abstracts Does Not Undercut the Reliability of His Methodology

Plaintiffs' argue that Dr. Shoemaker's physical properties opinions are unreliable because he "relied heavily on 'abstracts' of medical literature, as opposed to full peer-reviewed and published articles." This contention is also without a factual or legal basis.

During Dr. Shoemaker's deposition, Plaintiffs identified four abstracts upon which he relied in arriving at his opinions. One was a follow-up to an earlier article; another was an

abstract of an oral presentation. Dr. Shoemaker's reliance list includes more than 900 articles that he reviewed and relied upon in reaching his opinions. *See generally* Reliance List [Dkt. 4328-6]. That 4 among 900 were abstracts, does not render his opinions unreliable.

Second, there is no indication that Dr. Shoemaker "relied heavily" on abstracts versus articles as Plaintiffs argue. The testimony indicates that Dr. Shoemaker did not "rely heavily" on abstracts. To the contrary. Dr. Shoemaker specifically testified that the Cochrane meta-analyses served as his most prominent reliance material. *See* Shoemaker 07/21/17 Depo. [Dkt. 4328-4] 21:16-21:20 (stating a meta-analysis is "the highest level of studies that we have that I rely on"), 233:1-233:10 (describing his reliance on the Cochrane meta-analysis and referring to the Cochrane review as the "pinnacle" on the "pyramid of evidence").

C. Dr. Shoemaker's Reliance on His Clinical Experience and Literature Review Are Sufficiently Reliable to Arrive at the Opinion that Polypropylene Is Not Cytotoxic

Plaintiffs again argue that Dr. Shoemaker cannot rely upon his clinical experience to arrive at any opinions. *See* Pls.' Br. [Dkt. 4829] at 17. For the reasons discussed above, this is an incorrect statement of the law.

D. Dr. Shoemaker's Reliance on His Clinical Experience and Literature Review Are Sufficiently Reliable to Arrive at the Opinion that Degradation of Prolene, if Any, Is Not Clinically Significant

Plaintiffs argue that Dr. Shoemaker cannot opine on degradation. *See* Pls.' Br. [Dkt. 4329] at 18. Here, Plaintiffs misrepresent Dr. Shoemaker's opinions. Plaintiffs argue that Dr. Shoemaker is attempting to opine that degradation of Prolene is "impossible." *See id.* at 19. That is not what Dr. Shoemaker opines. Rather, he states that in his clinical experience and based upon his review of the medical literature, degradation (if it occurs) does not have any clinical significance. *See* Prolift Report [Dkt. 4328-2] at 39.

Dr. Shoemaker's clinical experience dealing with thousands of patients who have been implanted with these devices coupled with the medical literature demonstrating the lack of clinical significance of alleged degradation are sufficiently reliable to render his opinion that degradation (if it occurs) has no clinically significant effect. *See id.* at 39.

CONCLUSION

For the above reasons, Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson respectfully request that this Court enter an order denying Plaintiffs' Motion to Exclude or Otherwise Limit the Opinions and Testimony of Defense Expert Marshall Shoemaker, M.D. [Dkt. 4328].

Respectfully submitted,

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COUNSEL FOR DEFENDANTS ETHICON, INC., ETHICON, LLC, AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/Christy D. Jones

EXHIBIT

“A”

Gynecare

PROLIFT*

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

System til total reparation af bækkenbund
System til anterior reparation af bækkenbund
System til posterior reparation af bækkenbund

Systeem voor reparatie van de gehele bekkenbodem
Systeem voor reparatie van de anterieure bekkenbodem
Systeem voor reparatie van de posterieure bekkenbodem

Totaali lantionpohjan korjausjärjestelmä
Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä

Système pour cure de prolapsus total
Système pour cure de prolapsus antérieur
Système pour cure de prolapsus postérieur

Totalprolaps-Beckenboden-Rekonstruktionssystem
Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem

Sistema di riparazione totale del pavimento pelvico
Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico

Sistema de reparação do pavimento pélvico total
Sistema de reparação do pavimento pélvico anterior
Sistema de reparação do pavimento pélvico posterior

Sistema de reparación del suelo pélvico total
Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior

System för total reparation av bäckenbotten
System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten

Σύστημα ολικής αποκατάστασης πυελικού εδάφους
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους

Manufactured for:
GYNECARE WORLDWIDE
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits-Godet 20
CH-2000 Neuchâtel
Switzerland

P19070/E

ENGLISH

Gynecare

PROLIFT*

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROLIFT* Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training.

Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair Systems for further information on the GYNECARE PROLIFT procedures.

INDICATIONS

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

DESCRIPTION

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh implants and a set of instruments to facilitate mesh implant placement. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – GYNECARE PROLIFT Pelvic Floor Repair System Components

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS is mesh constructed of knitted filaments of extruded polypropylene identical in composition to PROLENE Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.). This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. The mesh affords excellent strength, durability, and surgical adaptability, with sufficient porosity for necessary tissue ingrowth. Blue PROLENE monofilaments have been incorporated to produce contrast striping in the mesh. The mesh is constructed of reduced diameter monofilament fibers, knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh. The mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This construction permits the mesh to be cut into any desired shape or size without unraveling. The bi-directional elastic property allows adaptation to various stresses encountered in the body.

Total Mesh Implant

The Total mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for performing a total vaginal repair. The implant has 6 straps: 4 for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends *(see Figure 1)*.

Anterior Mesh Implant

The Anterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of anterior vaginal defects. The implant has 4 straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively *(see Figure 1)*.

Posterior Mesh Implant

The Posterior mesh implant is constructed from GYNECARE GYNEMESH PS and is shaped for repair of posterior and/or apical vaginal vault defects. The implant has 2 straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the 2 posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends *(see Figure 1)*.

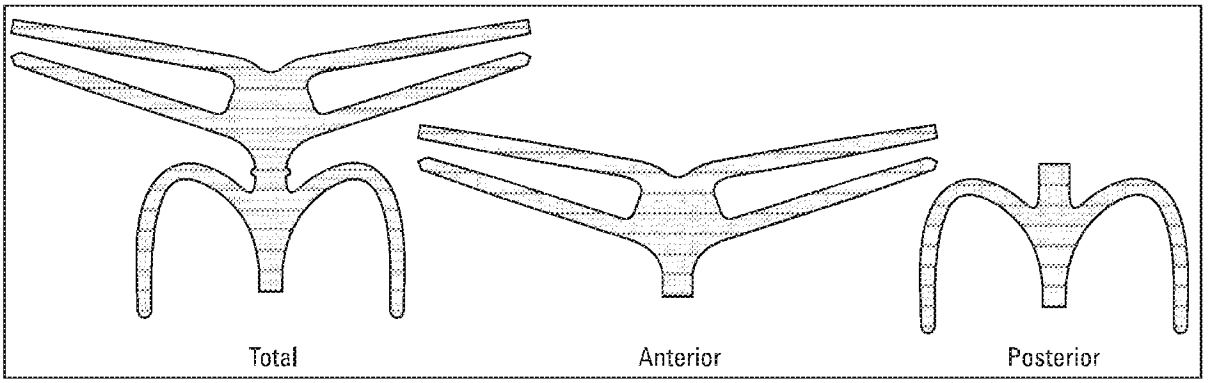


Figure 1 – Mesh Implants (Total, Anterior, and Posterior)

GYNECARE PROLIFT Guide

The GYNECARE PROLIFT Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior mesh implants and to facilitate placement of the GYNECARE PROLIFT Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT Guide is suitable for use on both sides of the patient *(see Figure 2)*.

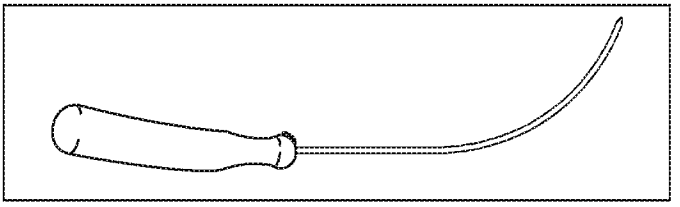


Figure 2 – GYNECARE PROLIFT Guide

GYNECARE PROLIFT Cannula

The GYNECARE PROLIFT Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT Cannula is placed over the GYNECARE PROLIFT Guide prior to passage and remains in place after the GYNECARE PROLIFT Guide is withdrawn *(see Figure 3)*.

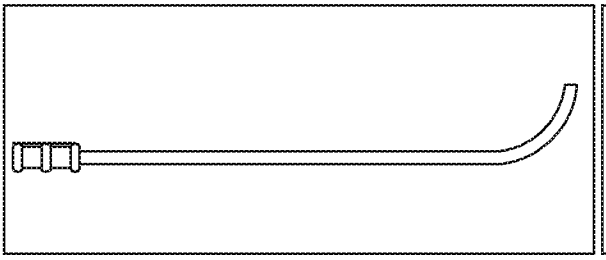


Figure 3 – GYNECARE PROLIFT Cannula

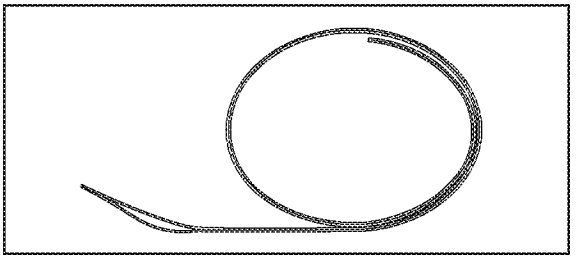


Figure 4 – GYNECARE PROLIFT Retrieval Device

GYNECARE PROLIFT Retrieval Device

The GYNECARE PROLIFT Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT Retrieval Device is passed through the previously positioned GYNECARE PROLIFT Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT Cannula *(see Figure 4)*.

INSTRUCTIONS FOR USE

NOTE: All figures below are not intended to provide any clinical teaching and only demonstrate the general use of each device.

Placement of the the GYNECARE PROLIFT Cannula onto the GYNECARE PROLIFT Guide ***(See Figures 5A and 5B)***

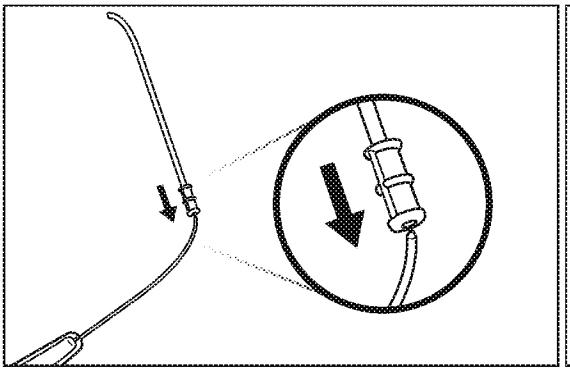


Figure 5A

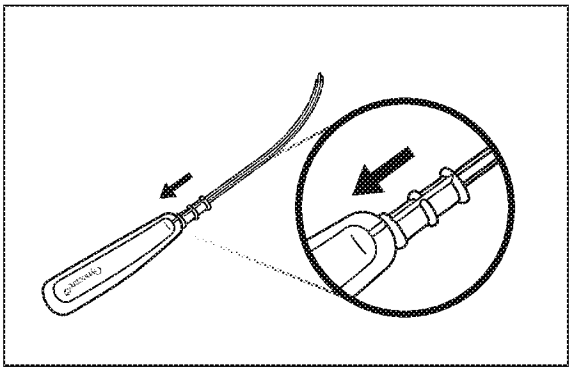


Figure 5B

IMPORTANT: Ensure proper alignment of GYNECARE PROLIFT Cannula and GYNECARE PROLIFT Guide upon assembly as demonstrated in *Figure 5B.*

Placement of the GYNECARE PROLIFT Cannula into the Patient ***(See Figures 6A , 6B and 6C)***

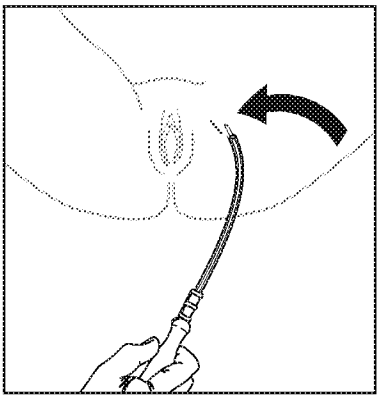


Figure 6A

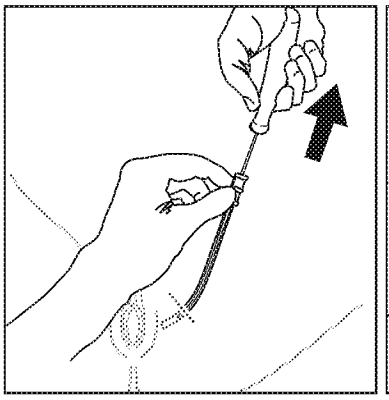


Figure 6B

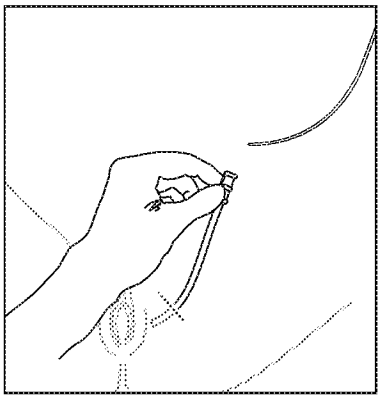


Figure 6C

Insertion and Passage of the GYNECARE PROLIFT Retrieval Device into the GYNECARE PROLIFT Cannula ***(See Figures 7A and 7B)***

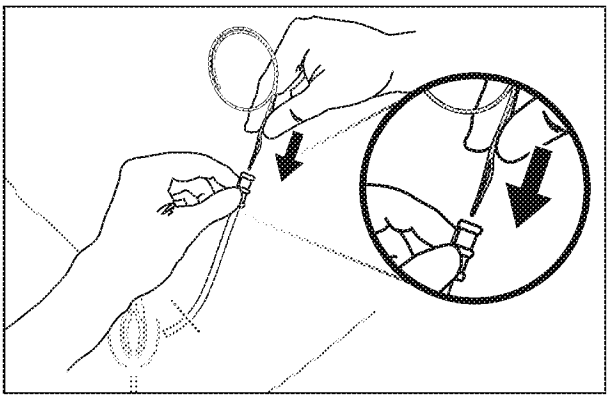


Figure 7A

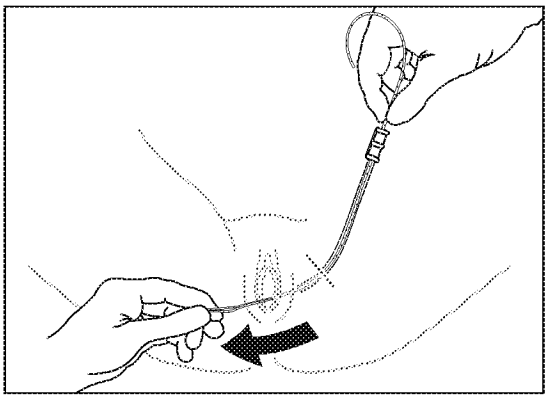


Figure 7B

IMPORTANT: All provided GYNECARE PROLIFT Cannulas and GYNECARE PROLIFT Retrieval Devices should be placed prior to mesh implant installation.

Capture of a Mesh Implant Strap with GYNECARE PROLIFT Retrieval Device ***(See Figures 8A , 8B and 8C)***

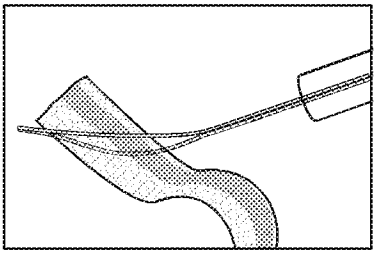


Figure 8A

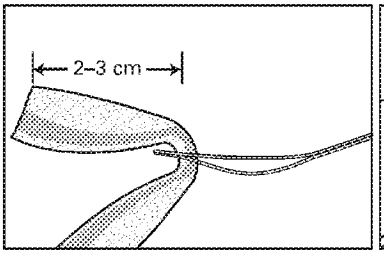


Figure 8B

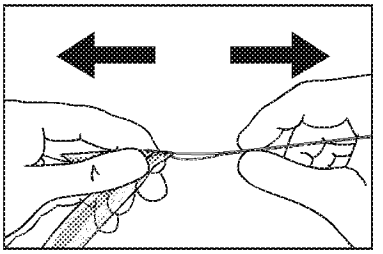


Figure 8C

Passage of a Mesh Implant Strap through the GYNECARE PROLIFT Cannula ***(See Figures 9A , 9B and 9C)***

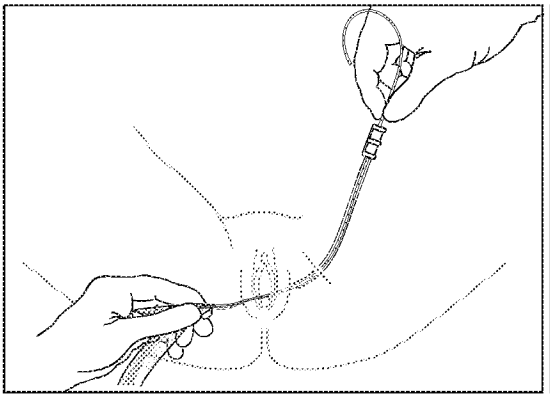


Figure 9A

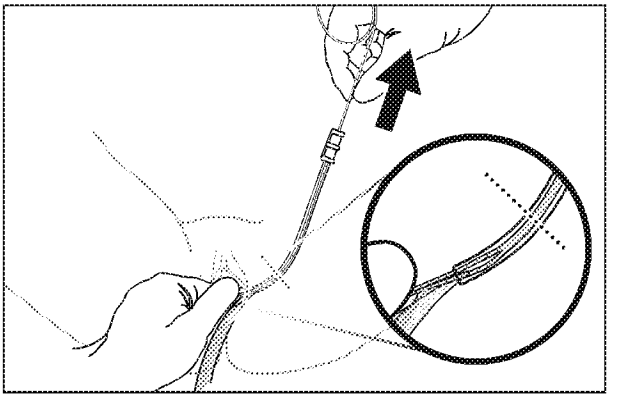


Figure 9B

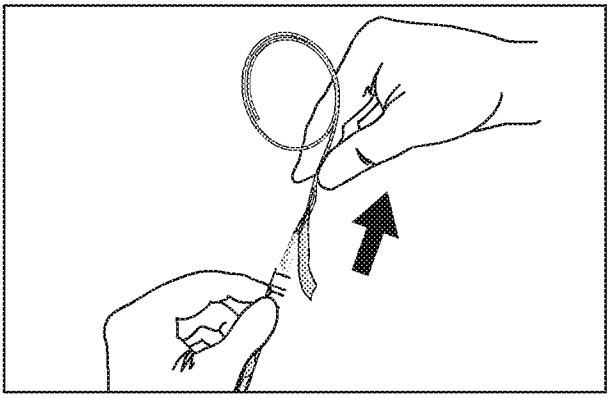


Figure 9C

IMPORTANT: Do not remove the GYNECARE PROLIFT Cannulas from the patient until the mesh implant has been properly positioned.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

PERFORMANCE

Animal studies show that implantation of GYNECARE GYNEMESH PS mesh elicits a minimum to slight inflammatory reaction, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

CONTRAINDICATIONS

When GYNECARE GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
- Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
- Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.
- Avoid placing excessive tension on the mesh implant during handling.
- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.
- The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.
- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

STERILITY

The GYNECARE PROLIFT Pelvic Floor Repair Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

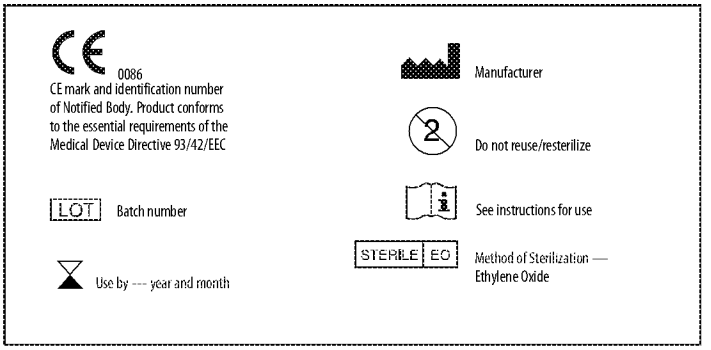
DISPOSAL

Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

Symbols Used on Labeling



DANSK

Gynecare

PROLIFT*

System til total reparation af bækkenbund
System til anterior reparation af bækkenbund
System til posterior reparation af bækkenbund

Læs venligst al information omhyggeligt.
Hvis anvisningerne ikke følges nøje, kan det resultere i, at produktet ikke fungerer korrekt og derved medfører personskade.

FORSIGTIG: Gældende lov (i USA) begrænser salget af dette produkt til læger eller på ordination af en læge.

Oplæring i anvendelsen af GYNECARE PROLIFT* systemerne til reparation af bækkenbunden anbefales og er tilgængelige. Kontakt firmaets salgsrepræsentant for at arrangere en sådan oplæring.

Der henvises til den anbefalede kirurgiske teknik i forbindelse med GYNECARE PROLIFT systemerne til reparation af bækkenbunden for yderligere oplysninger om GYNECARE PROLIFT procedurerne.

INDIKATIONER

GYNECARE PROLIFT systemerne til total, anterior eller posterior reparation af bækkenbunden er indikeret til forstærkning af væv og langvarig stabilisering af fasciale strukturer i bækkenbunden ved prolaps af vaginalvæggen, hvor kirurgisk behandling påtænkes, enten som mekanisk støtte eller brodannende materiale for den fasciale defekt.

BESKRIVELSE

GYNECARE PROLIFT systemerne til total, anterior eller posterior reparation af bækkenbunden består af et forskåret GYNECARE GYNEMESH* PS ikke-resorberbart PROLENE* blødt netimplantat og et sæt instrumenter, der gør det nemmere at anbringe netimplantatet. Tabellen herunder opsummerer de instrumenter, der følger med hvert system:

REPARATIONSSYSTEM	KOMPONENTER			
	Netimplantat	Guide	Tilbagetrækningsenheder	Kanyle
Total	1 total	1	6	6
Anterior	1 anterior	1	4	4
Posterior	1 posterior	1	2	2

Tabel 1 – Komponenter til GYNECARE PROLIFT system til reparation af bækkenbund

GYNECARE GYNEMESH PS

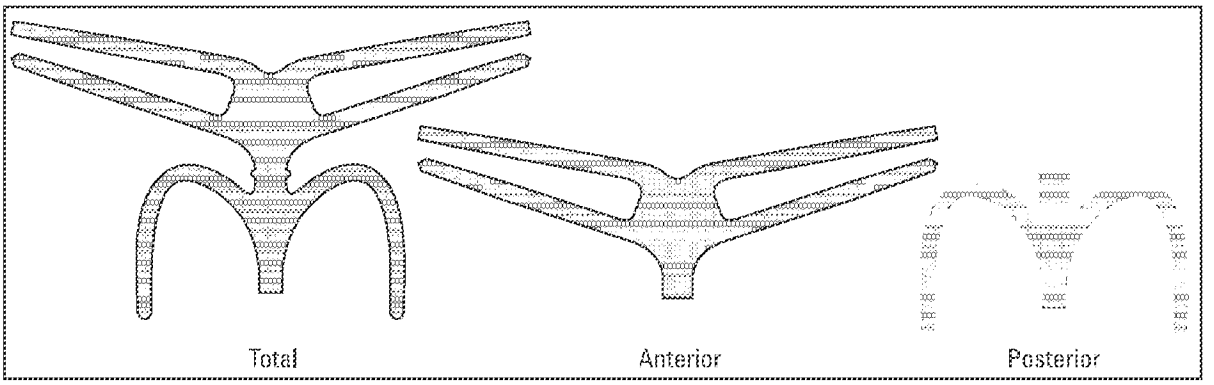
GYNECARE GYNEMESH PS er et net, der består af knyttede filamenter af ekstruderet polypropylen, som svarer til den sammensætning, der er anvendt i PROLENE-polypropylensutur, ikke-resorberbare operationssuturer, U.S.P. (ETHICON, INC.). Ved anvendelse til sutur er det rapporteret, at dette materiale er nonreaktivt, og at det bevarer styrken uendeligt ved klinisk anvendelse. Nettet besidder fortræffelige styrke-, holdbarheds- og operationstilpasningsevner med tilstrækkelig porøsitet til nødvendig indvækst af væv. Der er indlagt blå PROLENE-monofilamenter for at skabe kontraststriber i nettet. Nettet er konstrueret af monofilamentfibre med reduceret diameter, som er knyttet til et unikt design, hvilket resulterer i et net, der er cirka 50 procent mere fleksibelt end standard PROLENE-net. Nettet er knyttet vha. en proces, der sammenkæder hver enkelt fibersamling og giver elasticitet i begge retninger. Denne konstruktion gør det muligt at klippe nettet i enhver ønskelig form eller størrelse, uden at det trævler. Den dobbeltvirkende elastiske egenskab muliggør tilpasning til de forskellige belastninger, som kroppen udsætter det for.

Total netimplantat

Det totale netimplantat er fremstillet af GYNECARE GYNEMESH PS og formet til at udføre en total vaginalreparation. Implantatet har 6 stropper: 4 til fastgørelse af den anteriore del af implantatet via en transobturator-adgang, og 2 til fastgørelse af den posteriore del af implantatet i ligamentum sacrospinale via transgluteal adgang. Alternativt kan de 2 posteriore stropper kortes af og fastgøres i ligamentum sacrospinale via vaginal adgang. De proksimale og distale anteriore stropper har hhv. firkantede og trekantede ender, mens de posteriore stropper har afrundede ender *(se figur 1)*.

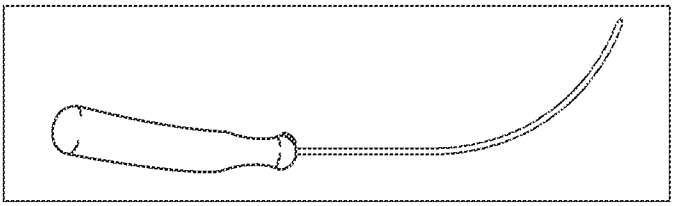
Anterior netimplantat
Det anteriore netimplantat er fremstillet af GYNECARE GYNEMESH PS og formet til reparation af anteriore vaginale defekter. Implantatet har 4 stropper, som fastgøres via transobturator-adgang. De proksimale og distale anteriore stropper har hhv. firkantede og trekantede ender *(se figur 1)*.

Posterior netimplantat
Det posteriore netimplantat er fremstillet af GYNECARE GYNEMESH PS og formet til reparation af posteriore og/eller apikale defekter af vaginaltoppen. Implantatet har 2 stropper, der fastgøres i ligamentum sacrospinale via transgluteal adgang. Alternativt kan de 2 posteriore stropper kortes af og fastgøres i ligamentum sacrospinale via vaginal adgang. De posteriore stropper har afrundede ender *(se figur 1)*.



Figur 1 – Netimplantater (total, anterior og posterior)

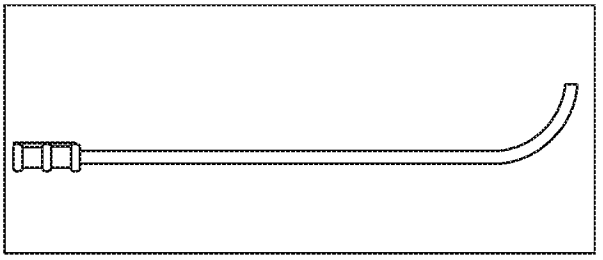
GYNECARE PROLIFT guide
GYNECARE PROLIFT guiden er et instrument til engangsbrug, som er udviklet til at skabe vævsgange, så et total, anterior eller posterior netimplantat kan anbringes, og for at gøre det nemmere at anbringe GYNECARE PROLIFT kanylen. Instrumentets længde og bøjning er specifikt udviklet til at frembringe passende anbringelsesgange til alle netimplantatstropper. GYNECARE PROLIFT guiden egner sig til anvendelse på begge sider af patienten *(se figur 2)*.



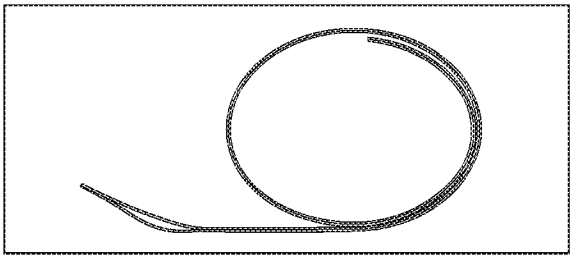
Figur 2 – GYNECARE PROLIFT guide

GYNECARE PROLIFT kanyle

GYNECARE PROLIFT kanylen er et instrument til engangsbrug, som bruges i forbindelse med GYNECARE PROLIFT guiden til at gøre fremføringen af implantatstropperne nemmere, og som samtidig beskytter det omkringliggende væv. Hver enkelt GYNECARE PROLIFT kanyle anbringes over GYNECARE PROLIFT guiden inden fremføringen og forbliver på plads, når GYNECARE PROLIFT guiden er trukket ud *(se figur 3)*.



Figur 3 – GYNECARE PROLIFT kanyle



Figur 4 – GYNECARE PROLIFT tilbagetrækningsenhed

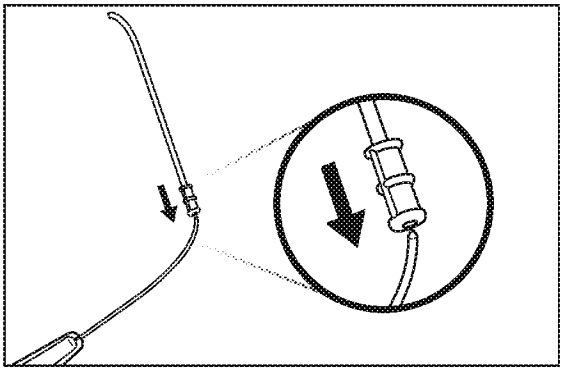
GYNECARE PROLIFT tilbagetrækningsenhed

GYNECARE PROLIFT tilbagetrækningsenheden er et instrument til engangsbrug, som er udviklet til at gøre det nemmere at anbringe netimplantatstropperne. GYNECARE PROLIFT tilbagetrækningsenheden føres gennem den allerede anbragte GYNECARE PROLIFT kanyle, indtil dens distale ende kan trækkes ud gennem den vaginale dissektion. Den distale ende af GYNECARE PROLIFT tilbagetrækningsenheden er forsynet med en løkke, som på sikker vis fastholder netimplantatstroppen, når denne trækkes ud gennem GYNECARE PROLIFT kanylen *(se figur 4)*.

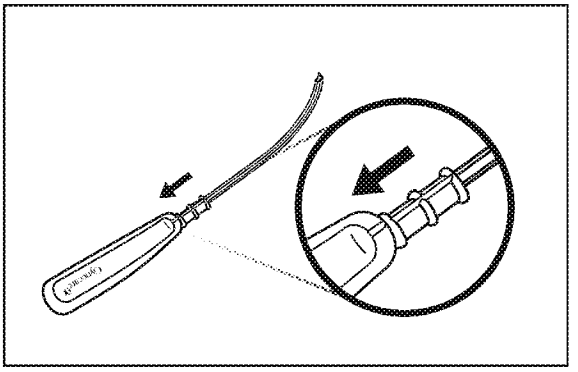
BRUGSANVISNING

BEMÆRK: Figurerne herunder er ikke beregnet til klinisk oplæring og viser kun den generelle anvendelse af de enkelte enheder.

Anbringelse af GYNECARE PROLIFT kanylen på GYNECARE PROLIFT guiden *(se figur 5A og 5B)*



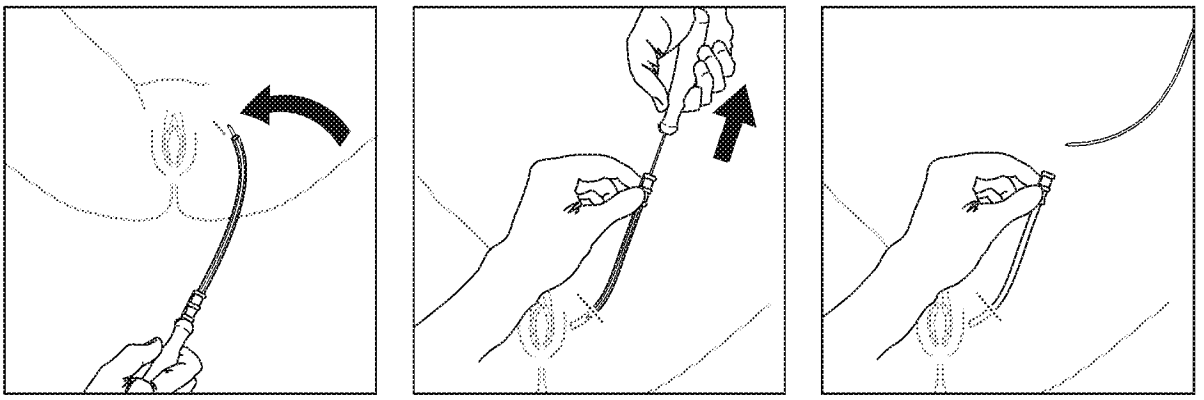
Figur 5A



Figur 5B

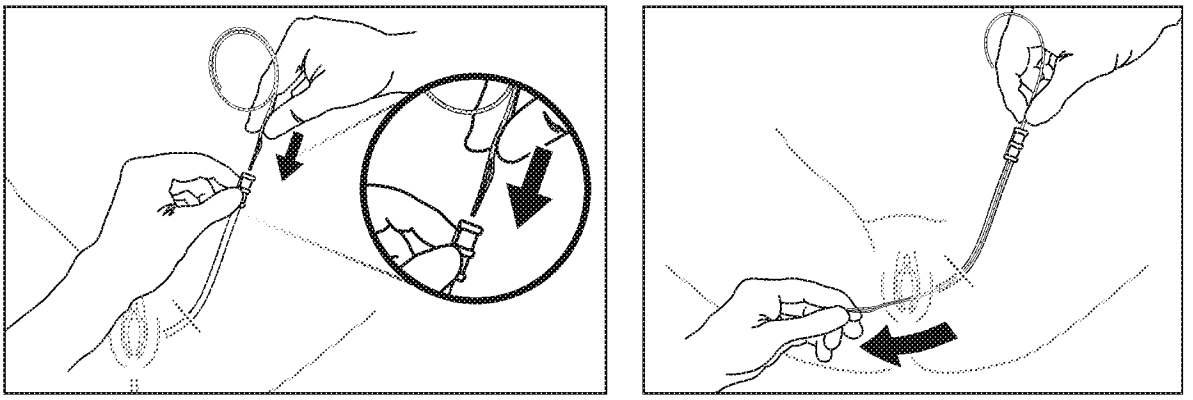
VIGTIGT: Sørg for, at GYNECARE PROLIFT kanylen og GYNECARE PROLIFT guiden rettes korrekt ind ved monteringen, som vist i *figur 5B*.

Anbringelse af GYNECARE PROLIFT kanylen i patienten ***(se figur 6A, 6B og 6C)***



Figur 6A ***Figur 6B*** ***Figur 6C***

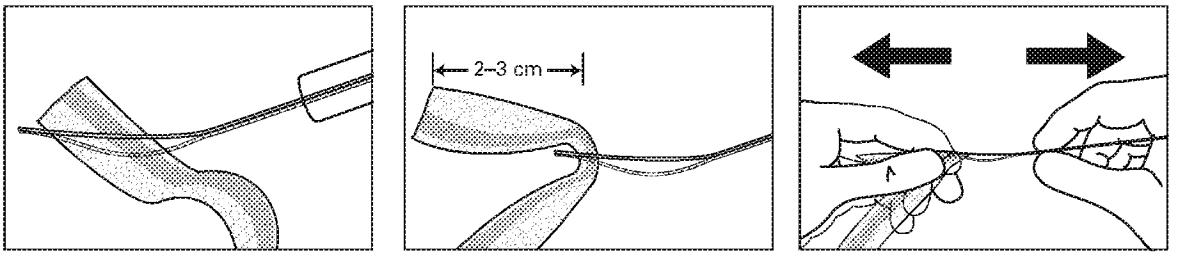
Ind- og fremføring af GYNECARE PROLIFT tilbagetrækningsenheden i GYNECARE PROLIFT kanylen ***(se figur 7A og 7B)***



Figur 7A ***Figur 7B***

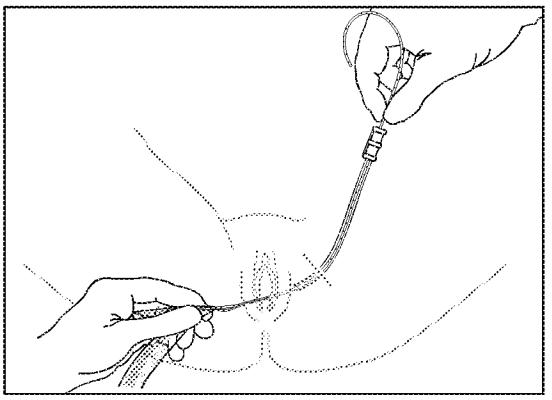
VIGTIGT: Alle medfølgende GYNECARE PROLIFT kanyler og GYNECARE PROLIFT tilbagetrækningsenheder skal anbringes, inden netimplantatet placeres.

Fastholdelse af en netimplantatstrop med GYNECARE PROLIFT tilbagetrækningsenheden ***(se figur 8A, 8B og 8C)***

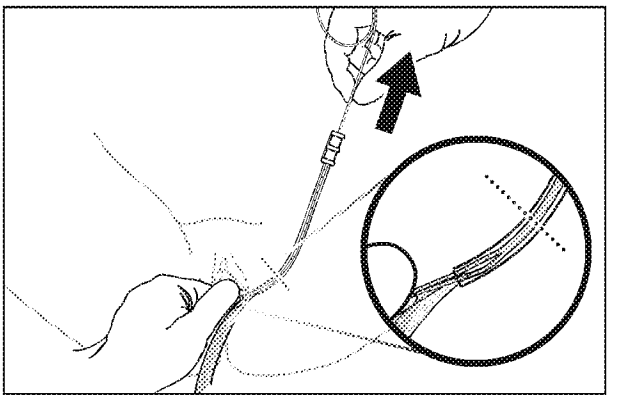


Figur 8A ***Figur 8B*** ***Figur 8C***

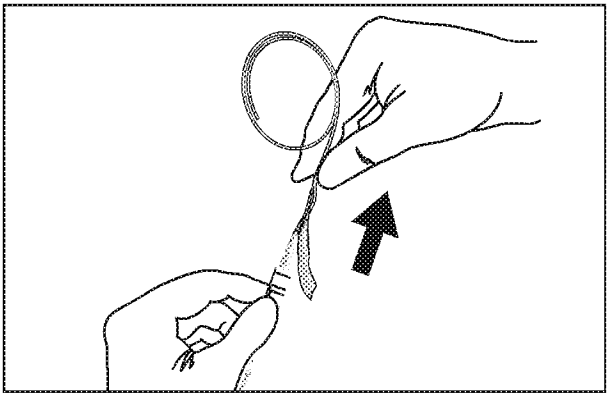
Transfer af en netimplantatstrop gennem GYNECARE PROLIFT kanylen ***(se figur 9A, 9B og 9C)***



Figur 9A



Figur 9B



Figur 9C

VIGTIGT: GYNECARE PROLIFT kanylerne må ikke fjernes fra patienten, før netimplantatet er korrekt anbragt.

Hvis suturer, staplere eller andet fikseringsudstyr anvendes i forbindelse med nettet, tilrådes det, at de anbringes mindst 6,5 mm fra nettets kant.

YDEEVNE

Dyreforsøg viser, at implantation af GYNECARE GYNEMESH PS net fremkalder en minimal til let inflammatorisk reaktion, som er kortvarig og efterfølges af dannelsen af et tyndt fibrøst vævslag, som kan vokse gennem nettets mellemrum og således inkorporere nettet i det tilstødende væv. Nettet forbliver blødt og smidigt, og den normale sårheling nedsættes ikke mærkbart. Materialet resorberes ikke, og det nedbrydes eller svækkes heller ikke af vævsenzymer.

KONTRAINDIKATIONER

Når GYNECARE GYNEMESH PS nettet anvendes på spædbørn, børn, gravide kvinder eller kvinder, der planlægger fremtidig graviditet, skal kirurgen være opmærksom på, at produktet ikke vil udvide sig signifikant, når patienten vokser.

ADVARSLER OG FORSIGTIGHEDSREGLER

- Før anvendelse af GYNECARE PROLIFT systemer til bækkenbundsreparation skal brugeren være fortrolig med de operationsprocedurer og -teknikker, der omfatter bækkenbundsreparation og ikke-resorberbare net.
- Tilfredsstillende operationspraksis skal følges ved tilstedeværelsen af inficerede eller kontaminerede sår.
- Efter operationen skal patienten informeres om, at samleje, løft af tunge ting og/eller motion (f.eks. cykling, jogging) skal undgås, indtil lægen vurderer, at patienten kan vende tilbage til sine normale aktiviteter.
- Undgå at stramme netimplantatet for meget, når det håndteres.
- Der henvises til den anbefalede kirurgiske teknik i forbindelse med GYNECARE PROLIFT systemet til bækkenbundsreparation for yderligere oplysninger om GYNECARE PROLIFT procedurerne.
- GYNECARE PROLIFT systemerne til bækkenbundsreparation skal anvendes med forsigtighed for at undgå beskadigelse af kar, nerver, blære og tarm. Opmærksomhed rettet mod patientens anatomi og korrekt anvendelse af anordningen vil minimere risici.
- Forbigående bensmerter kan forekomme og sædvanligvis behandles med et mildt analgetikum.
- GYNECARE PROLIFT tilbagetrækningsenheden må ikke manipuleres med skarpe instrumenter eller forsøges med en længdereducering.

BIVIRKNINGER

- Potentielle bivirkninger er de, der typisk forbindes med operativt implanterbare materialer, herunder potentielle infektioner, inflammation, adhæsions- og fisteldannelse, erosion, udstødelse og ardannelse, som medfører, at implantatet trækker sig sammen.
- Punkteringer eller lacerationer af kar, nerver, blære, urethra eller tarm kan opstå under fremføringen af GYNECARE PROLIFT guiden og eventuelt kræve operation.

STERILISERING

GYNECARE PROLIFT systemerne til bækkenbundsreparation er steriliserede med ethylenoxid. MÅ IKKE RESTERILISERES. MÅ IKKE GENBRUGES. Må ikke anvendes, hvis emballagen er åbnet eller beskadiget. Kassér alle åbnede, ubrugte produkter.

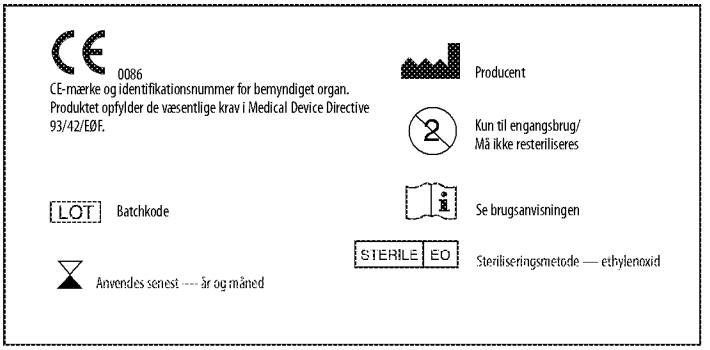
BORTSKAFFELSE

Bortskaf udstyret og indpakningen i henhold til institutionens politik og procedurer vedrørende biologisk farlige materialer og affald.

OPBEVARING

Anbefalede opbevaringsforhold: ved kontrolleret stuetemperatur og relativ fugtighed (ca. 25 °C, 60 % relativ fugtighed), beskyttet mod fugt og direkte varme. Må ikke anvendes efter, at udløbsdatoen er overskredet.

Symboler anvendt på mærkater



NEDERLANDS

Gynecare

PROLIFT*

Systeem voor reparatie van de gehele bekkenbodem
Systeem voor reparatie van de anterieure bekkenbodem
Systeem voor reparatie van de posterieure bekkenbodem

Lees alle informatie zorgvuldig.
Het negeren van deze instructies kan een ondoelmatige werking van de hulpmiddelen tot gevolg hebben en letsel veroorzaken.

LET OP: In de Verenigde Staten mag dit product alleen door of op voorschrift van een arts worden verkocht.

Gebruikers wordt geadviseerd, zich te oefenen in het gebruik van de GYNECARE PROLIFT* systemen voor bekkenbodemreparatie. Hiertoe zijn trainingsmogelijkheden beschikbaar. Neem voor het maken van afspraken voor zulke trainingen contact op met de vertegenwoordiger van uw leverancier.

Raadpleeg de aanbevolen chirurgische handleiding voor de GYNECARE PROLIFT bekkenbodemreparatiesystemen om meer informatie te verkrijgen over de GYNECARE PROLIFT procedures.

INDICATIES
De GYNECARE PROLIFT systemen voor reparatie van de gehele, anterieure en posterieure bekkenbodem zijn geïndiceerd voor weefselversterking en duurzame stabilisering van de bekkenbodem bij prolaps van de vaginawand waarvoor chirurgische behandeling wordt beoogd, als mechanische ondersteuning of als overbruggingsmateriaal voor het fasciadefect.

BESCHRIJVING
De GYNECARE PROLIFT systemen voor reparatie van de gehele, anterieure en posterieure bekkenbodem bestaan uit vooraf gesneden GYNECARE GYNEMESH* PS niet-resorbeerbare PROLENE* soft mesh-implantaten en een set instrumenten ter vergemakkelijking van de plaatsing van het mesh-implantaat. De onderstaande tabel biedt een overzicht van de instrumenten die van elk individueel systeem-pakket deel uitmaken:

REPARATIESYSTEEM	COMPONENTEN			
	Mesh-implantaat	Geleider	Doorhaal-instrumenten	Canules
Gehele bekkenbodem	1 totaal-implantaat	1	6	6
Anterieure bekkenbodem	1 anterieur-implantaat	1	4	4
Posterieure bekkenbodem	1 posterieur-implantaat	1	2	2

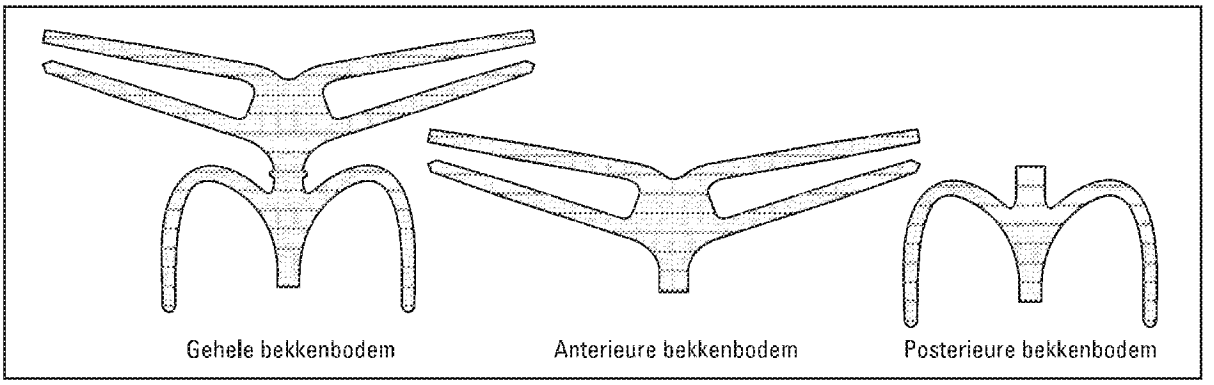
Tabel 1 – Componenten van de GYNECARE PROLIFT systemen voor reparatie van de bekkenbodem

GYNECARE GYNEMESH PS
GYNECARE GYNEMESH PS is meshmateriaal gemaakt van tricotvezels van geëxtrudeerd polypropyleen, qua samenstelling identiek aan PROLENE niet-resorbeerbaar chirurgisch polypropyleen hechtdraad, USP (ETHICON, INC.). Vastgesteld is dat dit materiaal bij gebruik als hechtmateriaal niet reactief is en dat het bij klinisch gebruik zijn kracht voor onbeperkte tijd behoudt. De mesh biedt een uitstekende sterkte, duurzaamheid en aanpasbaarheid voor chirurgische doeleinden en is voldoende poreus voor de noodzakelijke weefselingroei. Er is blauw PROLENE monofilamentmateriaal in het weefsel verwerkt, waardoor een contraststreep in de mesh ontstaat. De mesh is gemaakt volgens een uniek ontwerp van samengebreide monofilamentvezels met gereduceerde diameter, wat resulteert in een mesh die ongeveer 50 procent flexibeler is dan de standaard PROLENE meshes. De mesh wordt gebreid met gebruikmaking van een proces waardoor alle knooppunten van de vezels onderling met elkaar worden verbonden en waardoor er in beide richtingen elasticiteit wordt verschaft. Door deze constructie kan de mesh in iedere gewenste vorm en grootte worden geknipt zonder te rafelen. Door de elasticiteit in twee richtingen kan de mesh worden aangepast aan uiteenlopende spanningsbelastingen die in het lichaam voorkomen.

Totaal-meshimplantaat
Het totaal-meshimplantaat is vervaardigd van GYNECARE GYNEMESH PS en is zodanig gevormd dat er een totaal vaginale reparatie mee kan worden uitgevoerd. Het implantaat heeft 6 bevestigingsbandjes: vier voor het vastzetten van het voorste deel van het implantaat middels een transobturatorbenadering en twee voor het vastzetten van het achterste deel van het implantaat in het lig. sacrospinale middels een transgluteale benadering. Ook kunnen de twee posterieure bandjes door afknippen worden ingekort en middels een vaginale benadering in het lig. sacrospinale worden vastgezet. De uiteinden van de proximale en distale anterieure bandjes zijn respectievelijk vierkant en driehoekig van vorm, en de posterieure bandjes hebben een rond uiteinde *(zie afbeelding 1)*.

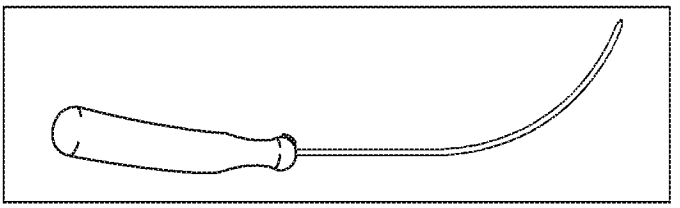
Anterieur meshimplantaat
Het meshimplantaat voor de anterieure bekkenbodem is vervaardigd van GYNECARE GYNEMESH PS en is zodanig gevormd dat er anterieure vaginale defecten mee kunnen worden gerepareerd. Het implantaat heeft vier bevestigingsbandjes, die middels een transobturatorbenadering worden vastgezet. De uiteinden van de proximale en distale anterieure bandjes zijn respectievelijk vierkant en driehoekig van vorm *(zie afbeelding 1)*.

Posterieur meshimplantaat
Het meshimplantaat voor de posterieure bekkenbodem is vervaardigd van GYNECARE GYNEMESH PS en is zodanig gevormd dat er posterieure en/of apicale defecten van het vaginagewelf mee kunnen worden gerepareerd. Het implantaat heeft twee bevestigings-bandjes, die middels een transgluteale benadering in het lig. sacrospinale worden vastgezet. Ook kunnen de twee posterieure bandjes door afknippen worden ingekort en middels een vaginale benadering in het lig. sacrospinale worden vastgezet. De bevestigingsbandjes van het posterieure meshimplantaat hebben ronde uiteinden *(zie afbeelding 1)*.



Afbeelding 1 – Meshimplantaten (voor de gehele, de anterieure en de posterieure bekkenbodem)

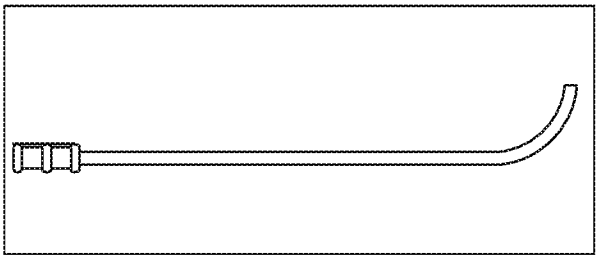
GYNECARE PROLIFT geleider
De GYNECARE PROLIFT geleider is een instrument voor eenmalig gebruik, met als toepassingsdoelen het tot stand brengen van weefseltrajecten waarlangs de meshimplantaten voor de gehele, anterieure en posterieure bekkenbodem kunnen worden geplaatst, en vergemakkelijking van het plaatsen van de GYNECARE PROLIFT canule. De lengte en kromming van de geleider zijn zodanig ontworpen dat voor alle implantaatbandjes goed passende plaatsingstrajecten worden verschaft. De GYNECARE PROLIFT geleider kan aan beide zijden van de anatomie van de patiënt worden gebruikt *(zie afbeelding 2)*.



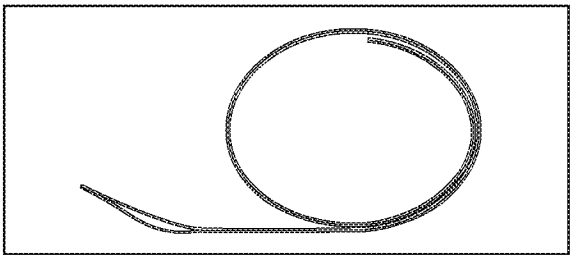
Afbeelding 2 – GYNECARE PROLIFT geleider

GYNECARE PROLIFT canule

De GYNECARE PROLIFT canule is een instrument voor eenmalig gebruik, dat in combinatie met de GYNECARE PROLIFT geleider dienst doet ter vergemakkelijking van de doorvoer van de implantaatbandjes en ter bescherming van het omliggende weefsel. De GYNECARE PROLIFT canule wordt over de GYNECARE PROLIFT geleider geschoven voordat de geleider wordt ingebracht, en blijft op zijn plaats nadat de GYNECARE PROLIFT geleider is teruggetrokken *(zie afbeelding 3)*.



Afbeelding 3 – GYNECARE PROLIFT canule



Afbeelding 4 – GYNECARE PROLIFT doorhaalinstrument

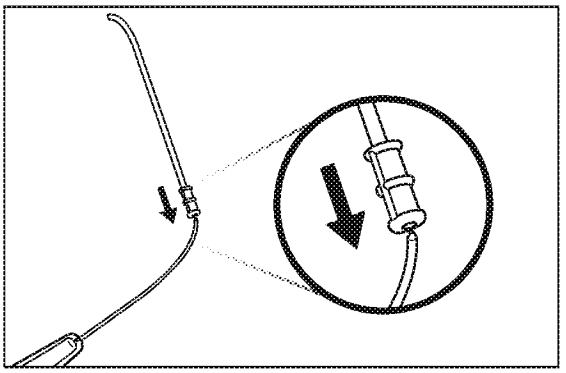
GYNECARE PROLIFT doorhaalinstrument

Het GYNECARE PROLIFT doorhaalinstrument is een hulpmiddel voor eenmalig gebruik, met als doel het vergemakkelijken van de plaatsing van de meshimplantaatbandjes. Het GYNECARE PROLIFT doorhaalinstrument wordt door de eerder geplaatste GYNECARE PROLIFT canule opgevoerd totdat het distale uiteinde van het doorhaalinstrument door het losgeprepareerde vaginale weefsel uittreedt. Het distale uiteinde van het GYNECARE PROLIFT doorhaalinstrument is voorzien van een lus, waarmee het bevestigingsbandje van het meshimplantaat stevig kan worden vastgehouden terwijl het bandje via de GYNECARE PROLIFT canule naar buiten wordt getrokken *(zie afbeelding 4)*.

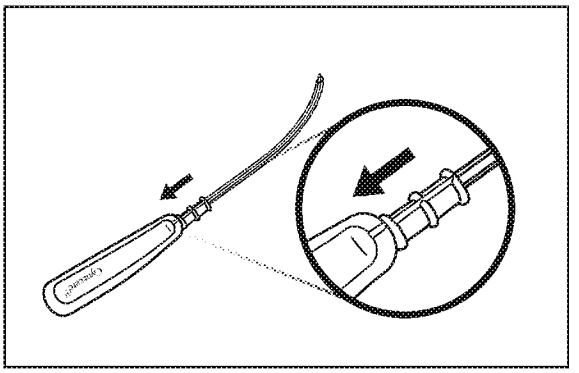
GEBRUIKSAANWIJZING

OPMERKING: De onderstaande afbeeldingen hebben niet als doel, klinisch onderricht te verschaffen. Zij dienen slechts als illustratie van het algemeen gebruik van de onderscheiden hulpmiddelen.

Plaatsing van de GYNECARE PROLIFT canule op de GYNECARE PROLIFT geleider *(zie afbeeldingen 5A en 5B)*



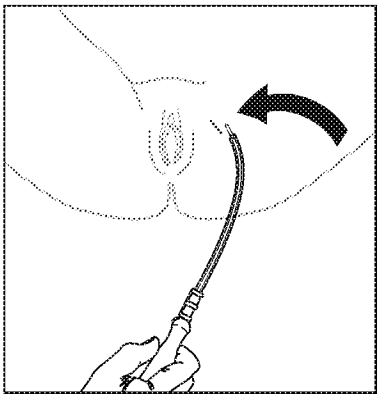
Afbeelding 5A



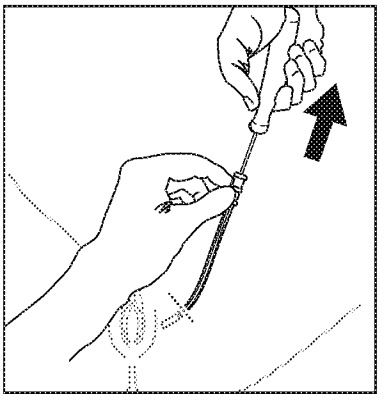
Afbeelding 5B

BELANGRIJK: Zorg dat de GYNECARE PROLIFT canule en de GYNECARE PROLIFT geleider bij het samenvoegen goed op elkaar lijnen, zoals afgebeeld in *afbeelding 5B*.

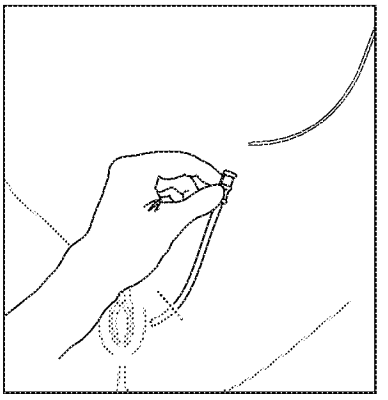
Het inbrengen van de GYNECARE PROLIFT canule in het lichaam van de patiënt ***(zie afbeeldingen 6A, 6B en 6C)***



Afbeelding 6A

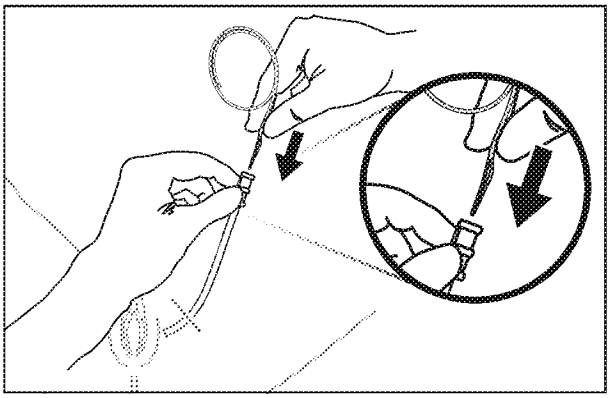


Afbeelding 6B

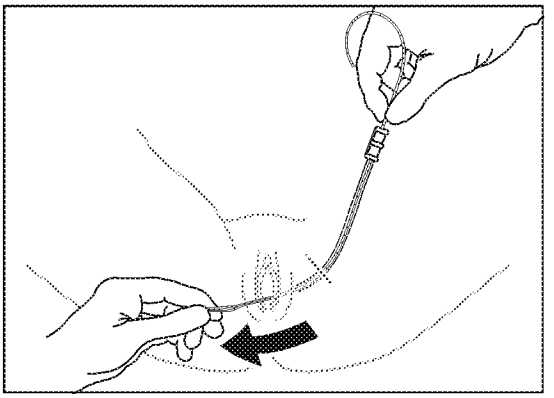


Afbeelding 6C

Insertie en doorvoer van het GYNECARE PROLIFT doorhaalinstrument in de GYNECARE PROLIFT canule ***(zie afbeeldingen 7A en 7B)***



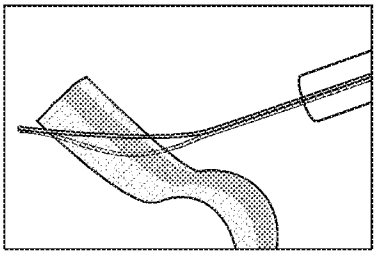
Afbeelding 7A



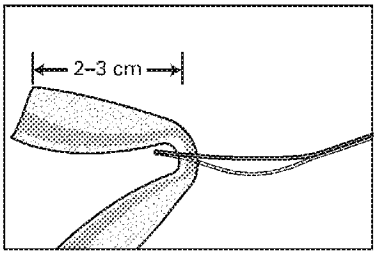
Afbeelding 7B

BELANGRIJK: Alle GYNECARE PROLIFT canules en GYNECARE PROLIFT doorhaalinstrumenten moeten worden geplaatst voordat het meshimplantaat wordt ingebracht.

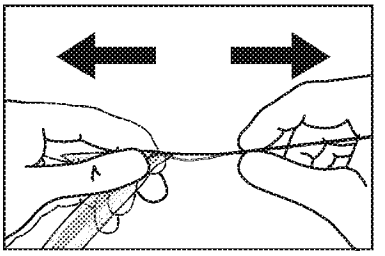
Een meshimplantaat-bevestigingsbandje vasthouden met een GYNECARE PROLIFT doorhaalinstrument ***(zie afbeeldingen 8A, 8B en 8C)***



Afbeelding 8A

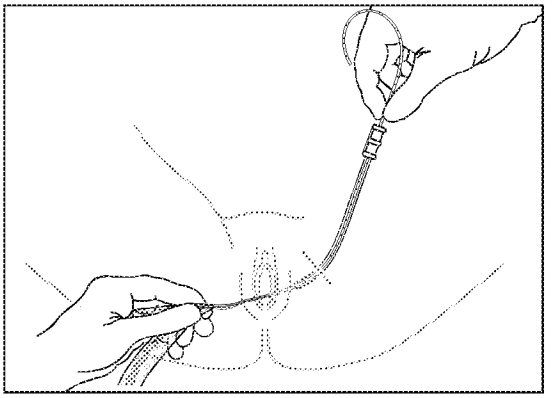


Afbeelding 8B

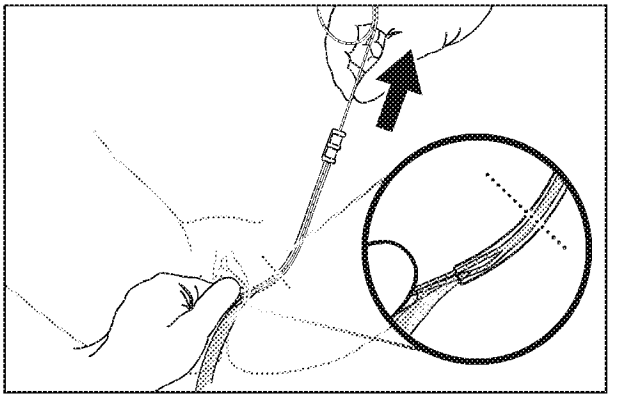


Afbeelding 8C

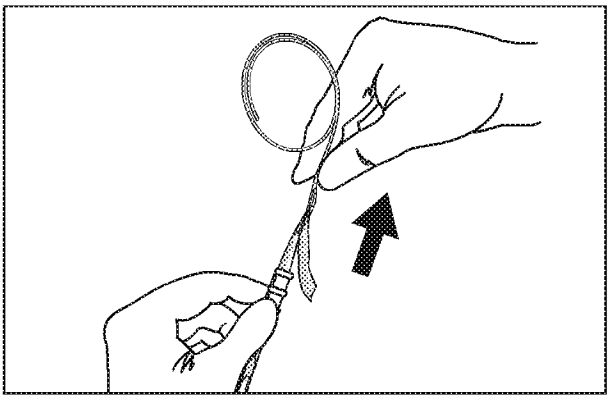
Doorvoer van een meshimplantaat-bevestigingsbandje door de GYNECARE PROLIFT canule ***(zie afbeeldingen 9A, 9B en 9C)***



Afbeelding 9A



Afbeelding 9B



Afbeelding 9C

BELANGRIJK: Neem de GYNECARE PROLIFT canules pas uit het lichaam van de patiënt nadat het meshimplantaat in de goede positie is geplaatst.

Wanneer in combinatie met het meshmateriaal gebruik wordt gemaakt van hechtingen, staples of andere fixatiehulpmiddelen, is het raadzaam deze op minstens 6,5 mm afstand van de rand van het meshimplantaat te plaatsen.

WERKINGSEIGENSCHAPPEN

Onderzoek bij proefdieren toont aan dat implantatie van een GYNECARE GYNEMESH PS meshimplantaat een minimale tot lichte ontstekingsreactie opwekt, die van voorbijgaande aard is en wordt gevolgd door afzetting van een dun laagje bindweefsel dat door de openingen in de mesh kan groeien, zodat de mesh in het naastliggende weefsel wordt opgenomen. De mesh blijft zacht en buigzaam en de normale wondgenezing wordt niet merkbaar belemmerd. Het materiaal wordt niet geresorbeerd en is evenmin onderhevig aan afbreking of verzwakking door de werking van weefselenzymen.

CONTRA-INDICATIES

Als GYNECARE GYNEMESH PS mesh wordt gebruikt bij zuigelingen, kinderen, zwangere vrouwen of vrouwen die in de toekomst nog zwanger wensen te worden, dient de chirurg zich ervan bewust te zijn dat de mesh niet noemenswaardig zal meerekken bij groei van de patiënt.

WAARSCHUWINGEN EN VOORZORGSMAATREGELEN

- Gebruikers dienen vertrouwd zijn met de chirurgische procedures en technieken samenhangend met reconstructie van de bekkenbodem en met niet-resorbeerbare meshes voordat GYNECARE PROLIFT SYSTEMEN voor bekkenbodemreparatie worden gebruikt.
- Voor behandeling van geïnfecteerde of gecontamineerde wonden moet van algemeen aanvaarde chirurgische methoden gebruik worden gemaakt.
- De patiënt moet worden geïnstrueerd om zich na de operatie te onthouden van seksuele gemeenschap, het tillen van zware voorwerpen en/of andere lichamelijke inspanningen (b.v. fietsen of joggen), totdat de arts het verantwoord acht dat de patiënt haar normale activiteiten hervat.
- Vermijd dat er tijdens de plaatsing overmatige druk- of trekspanning op het meshimplantaat wordt uitgeoefend.
- Raadpleeg de aanbevolen chirurgische handleiding voor het GYNECARE PROLIFT bekkenbodemreparatiesysteem om meer informatie te verkrijgen over de GYNECARE PROLIFT procedures.
- Bij het werken met GYNECARE PROLIFT bekkenbodemreparatiesystemen moet contact met bloedvaten, zenuwen, blaas en darmen zorgvuldig worden vermeden. Door aandacht te besteden aan de anatomie van de patiënt en aan een correct gebruik van het hulpmiddel houdt men de risico's minimaal.
- Er kan voorbijgaande pijn in de benen optreden. Deze kan doorgaans worden behandeld met lichte pijnstillers.
- Manipuleer het GYNECARE PROLIFT doorhaalinstrument niet met scherpe instrumenten en knip er geen delen af om de lengte te veranderen.

BIJWERKINGEN

- Mogelijke ongewenste reacties zijn de bij chirurgisch implanteerbare materialen gangbare reacties, zoals verhoogde infectiekans, ontsteking, vorming van adhesies, vorming van fistels, erosie, uitstoting van het implantaat en contractie van het implantaat als gevolg van littekenvorming.
- Tijdens het inbrengen van de GYNECARE PROLIFT geleider kan zich punctuur of laceratie van bloedvaten, zenuwen, blaas of darmen voordoen. Dit vergt mogelijk operatieve reparatie.

STERILITEIT

De GYNECARE PROLIFT bekkenbodemreparatiesystemen zijn met ethyleenoxide gesteriliseerd. NIET OPNIEUW STERILISEREN. NIET OPNIEUW GEBRUIKEN. Niet gebruiken wanneer de verpakking geopend of beschadigd is. Werp geopende en niet gebruikte hulpmiddelen altijd weg.

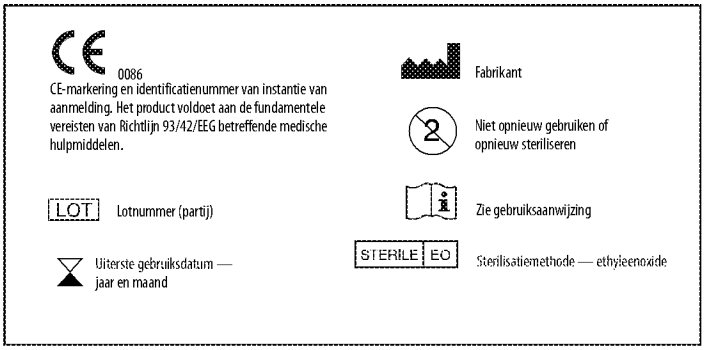
AFVOER

Voer de hulpmiddelen en verpakkingsmaterialen af volgens in uw instelling van kracht zijnde beleidslijnen en procedures met betrekking tot biologisch gevaarlijk materiaal en afval.

OPSLAG

Aanbevolen omstandigheden voor opslag: regelbare kamertemperatuur en relatieve luchtvochtigheid (temperatuur ca. 25 °C, relatieve luchtvochtigheid ca. 60%), op veilige afstand van vocht en directe hitte. Niet gebruiken na de uiterste gebruiksdatum.

Op etiketten en in productdocumentatie gebruikte symbolen



SUOMI

Gynecare

PROLIFT*

Totaali lantionpohjan korjausjärjestelmä
Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä

Lue kaikki ohjeet huolellisesti.

Ohjeiden laiminlyöminen saattaa johtaa laitteiden virheelliseen toimintaan ja potilasvahinkoon.

HUOMIO: Yhdysvaltain liittovaltion lain mukaan tämän tuotteen saa myydä ainoastaan lääkäri tai lääkärin määräyksestä.

Lantionpohjan GYNECARE PROLIFT* -korjausjärjestelmien käyttöön tutustuminen on suositeltua ja koulutusta tähän tarkoitukseen on järjestettävissä. Lisätietoja koulutusohjelmasta saa yhtiön myyntiedustajalta.

Lisätietoja GYNECARE PROLIFT -toimenpiteistä on lantionpohjan GYNECARE PROLIFT -korjausjärjestelmien kirurgisten menetelmien kuvauksissa.

INDIKAATIOT

Totaalit, anterioriset ja posterioriset GYNECARE PROLIFT -korjausjärjestelmät on tarkoitettu kudoksen tukemiseen ja lantionpohjan sidekudoskalvorakenteiden pitkäaikaiseen stabilointiin emättimen seinämän laskeuman kirurgisessa hoidossa. Se toimii joko sidekudosvamman mekaanisena tukena tai siltamateriaalina.

KUVAUS

Totaalit, anterioriset ja posterioriset GYNECARE PROLIFT -lantionpohjan korjausjärjestelmät koostuvat valmiiksi muotoon leikatuista resorboitumattomista ja pehmeistä GYNECARE GYNEMESH* PS PROLENE*-verkkoimplanteista ja instrumenttisarjasta, jotka helpottavat verkkoimplantin sijoittamista. Seuraavassa taulukossa on yhteenveto eri järjestelmien mukana toimitettavista instrumenteista:

KORJAUSJÄRJESTELMÄ	OSAT			
	Verkkoimplantti	Ohjain	Noutosilmukat	Kanyylit
Totaali	1 totaali	1	6	6
Anteriorinen	1 anteriorinen	1	4	4
Posteriorinen	1 posteriorinen	1	2	2

Taulukko 1 – Lantionpohjan GYNECARE PROLIFT -korjausjärjestelmän osat

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS -verkko on valmistettu puristetusta polypropyleenineulekudoksesta, joka on koostumukseltaan samanlainen kuin resorboitumattomat kirurgiset PROLENE-polypropyleeniommelaineet, U.S.P. (ETHICON, INC.). Tämän materiaalin ei ole todettu ommellankana käytettäessä aiheuttavan kudosreaktioita ja se pysyy kliinisessä käytössä pysyvästi muuttumattomana. Verkko on erittäin vahva, kestävä ja kirurgisesti monikäyttöinen, ja se on riittävän huokoinen kudoskasvulle. Verkkoon on lisätty sinisiä, yksisäikeisiä PROLENE-kuituja kontrastiraidoituksen aikaansaamiseksi. Verkko on valmistettu läpimitaltaan redusoiduista yksisäikeisistä kuiduista ja kudottu ainutlaatuisella menetelmällä verkoksi, joka on noin 50 prosenttia joustavampi kuin normaali PROLENE-verkko. Verkko on kudottu menetelmällä, joka liittää yhteen jokaisen säikeen haaran, minkä ansiosta se joustaa molempiin suuntiin. Tämän rakenteen ansiosta verkkoa voidaan leikata minkä tahansa muotoiseksi tai kokoiseksi sen rispaantumatta. Molempisuuntaisen joustavuuden ansiosta verkko sopeutuu moniin erityyppisiin kehon rasituksiin.

Totaali verkkoimplantti

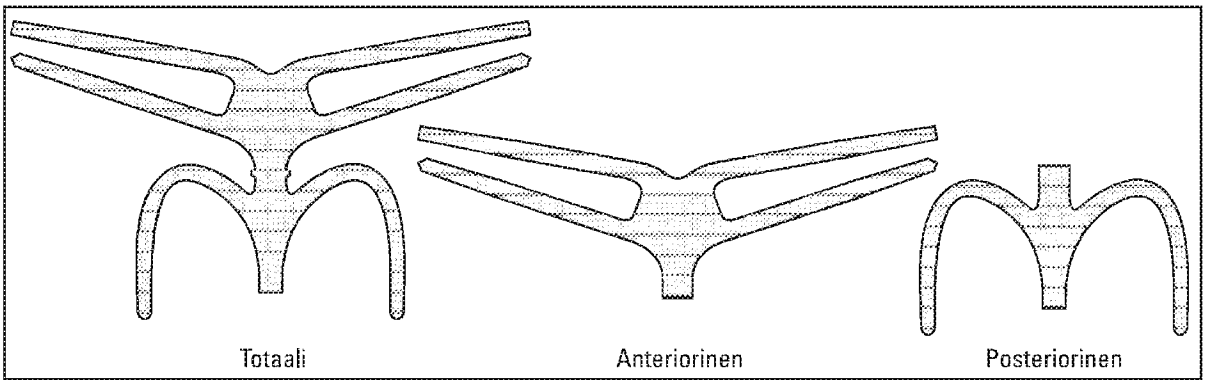
Totaali verkkoimplantti on valmistettu GYNECARE GYNEMESH PS -materiaalista ja muotoiltu totaaliin emättimen korjaustoimenpiteeseen. Implantissa on 6 kiinnitysnauhaa: neljä kiinnitysnauhaa anteriorisen implanttiosan kiinnittämiseen transobturaattorista lähestymistapaa käyttäen ja kaksi kiinnitysnauhaa posteriorisen implanttiosan kiinnittämiseen ristiluu-selkärankasiteeseen transgluteaalista lähestymistapaa käyttäen. Vaihtoehtoisesti kahta (2) posteriorista kiinnitysnauhaa voidaan leikata lyhyemmiksi ja kiinnittää ristiluu-selkärankasiteeseen emättimen kautta. Proksimaalisissa kiinnitysnauhoissa on neliönmuotoiset ja distaalisissa anteriorisissa kiinnitysnauhoissa kolmionmuotoiset päät, ja posteriorisissa kiinnitysnauhoissa pyöristetyt päät *(kuva 1)*.

Anteriorinen verkkoimplantti

Anteriorinen verkkoimplantti on valmistettu GYNECARE GYNEMESH PS -materiaalista ja muotoiltu anteriorisiin emättimen korjaustoimenpiteeseen. Implantissa on neljä kiinnitysnauhaa, jotka kiinnitetään transobturaattorista lähestymistapaa käyttäen. Anterioristen kiinnitysnauhojen proksimaalipäissä on neliönmalliset ja distaalipäissä kolmionmalliset päät *(kuva 1)*.

Posteriorinen verkkoimplantti

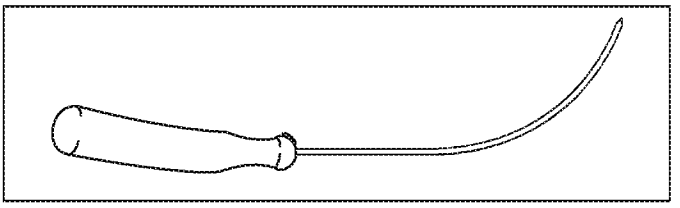
Posteriorinen verkkoimplantti on valmistettu GYNECARE GYNEMESH PS -materiaalista ja muotoiltu posteriorisiin ja/tai apikaalisiin emättimen laskeuman korjaustoimenpiteeseen. Implantissa on kaksi kiinnitysnauhaa, jotka kiinnitetään ristiluu-selkärankasiteeseen transgluteaalista lähestymistapaa käyttäen. Vaihtoehtoisesti kahta posteriorista kiinnitysnauhaa voidaan leikata lyhyemmiksi ja kiinnittää ristiluu-selkärankasiteeseen emättimen kautta. Posteriorisissa kiinnitysnauhoissa on pyöristetyt päät *(kuva 1)*.



Kuva 1 – Verkkoimplantit (totaali, anteriorinen ja posteriorinen)

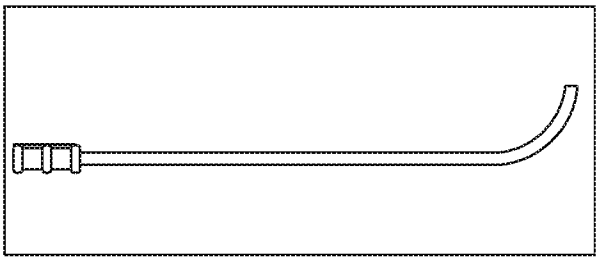
GYNECARE PROLIFT -ohjain

GYNECARE PROLIFT -ohjain on kertakäyttöinen ja potilaskohtainen instrumentti, joka on tarkoitettu käytettäväksi kudosreitin aikaansaamiseen totaalin, anteriorisen ja posteriorisen verkkoimplantin sijoittamisen ja GYNECARE PROLIFT -kanyylin sijoittamisen helpottamiseksi. Sen pituus ja kaarevuus on suunniteltu erityisesti asianmukaisten sijoitusreittien aikaansaamiseen kaikkia verkkoimplanttinauhoja varten. GYNECARE PROLIFT -ohjain sopii käytettäväksi potilaan molemmilla puolilla *(kuva 2)*.

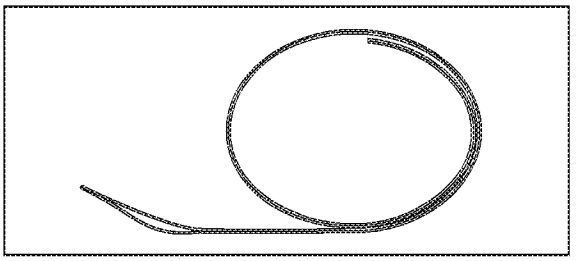


Kuva 2 – GYNECARE PROLIFT -ohjain

GYNECARE PROLIFT -kanyyli
GYNECARE PROLIFT -kanyyli on potilaskohtainen kertakäyttöinen instrumentti, jota käytetään yhdessä GYNECARE PROLIFT -ohjaimen kanssa avustamaan implanttinauhojen reitittämisessä ympäröivää kudosta suojaten. GYNECARE PROLIFT -kanyyli sijoitetaan GYNECARE PROLIFT -ohjainta pitkin ja se jätetään paikalleen, kun GYNECARE PROLIFT -ohjain vedetään pois *(kuva 3)*.



Kuva 3 – GYNECARE PROLIFT -kanyyli

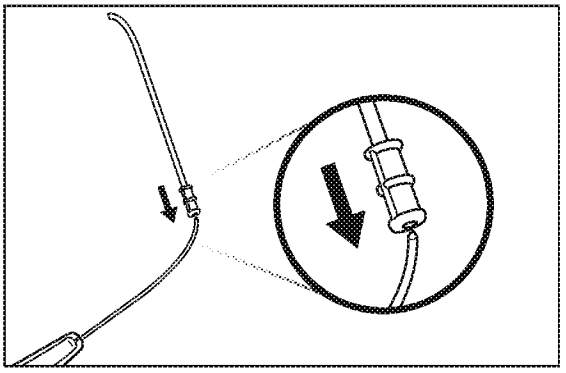


Kuva 4 – GYNECARE PROLIFT -noutosilmukka

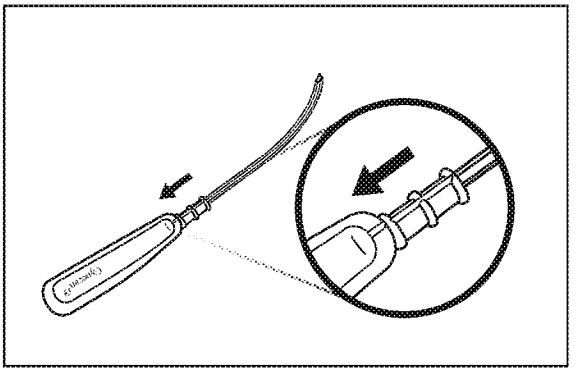
GYNECARE PROLIFT -noutosilmukka
GYNECARE PROLIFT -noutosilmukka on potilaskohtainen kertakäyttöinen instrumentti, joka on tarkoitettu avustamaan verkkoimplantti-nauhojen sijoittamisessa. GYNECARE PROLIFT -noutosilmukka viedään aiemmin sijoitetun GYNECARE PROLIFT -kanyylin kautta kunnes sen distaalipää tulee ulos emättimen avausviillosta. GYNECARE PROLIFT -noutosilmukan distaalipäässä on silmukka, joka sitoo verkkoimplanttinauhan tukevasti, kun se vedetään ulos GYNECARE PROLIFT -kanyylin kautta *(kuva 4)*.

KÄYTTÖOHJEET
HUOMAUTUS: Alla olevia kuvia ei ole tarkoitettu kirurgiseen koulutukseen, vaan ne kuvaavat kunkin laitteen yleistä käyttötarkoitusta.

GYNECARE PROLIFT -kanyylin sijoittaminen GYNECARE PROLIFT -ohjaimeen *(kuvat 5A ja 5B)*



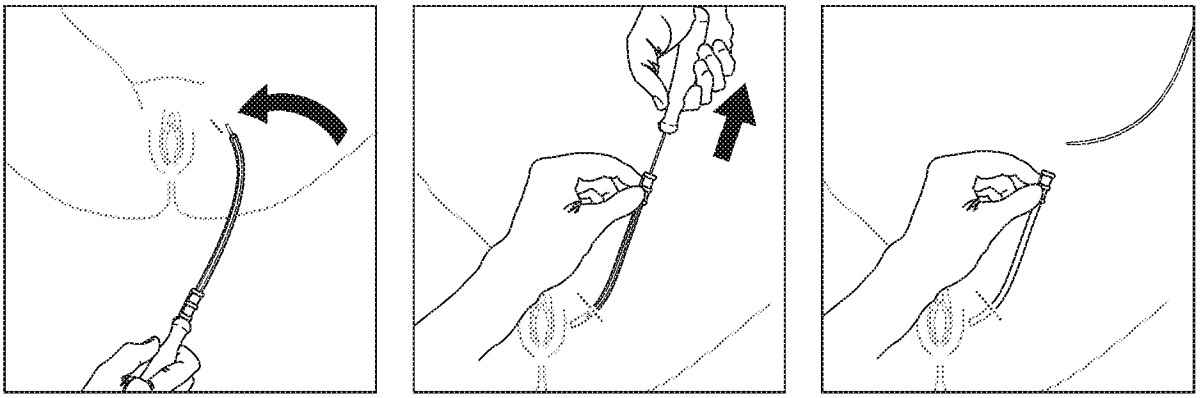
Kuva 5A



Kuva 5B

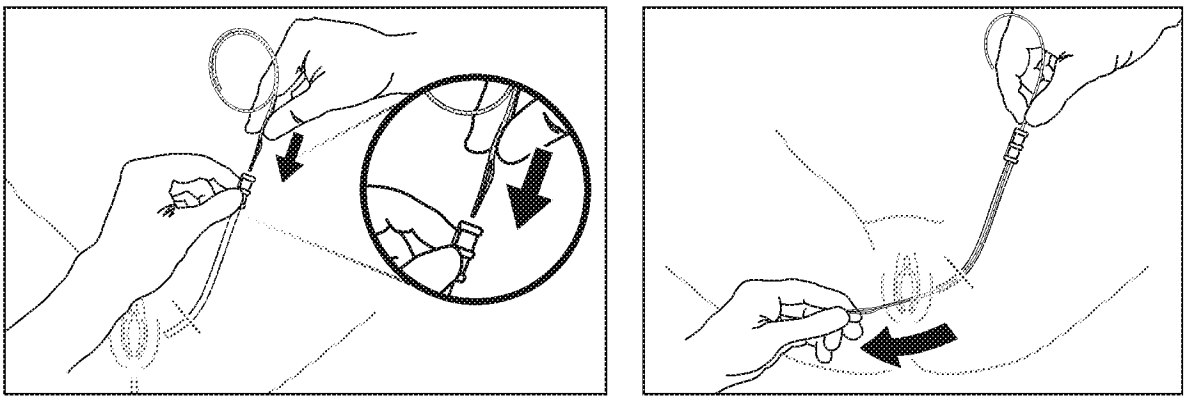
TÄRKEÄÄ: Varmista GYNECARE PROLIFT -kanyylin ja GYNECARE PROLIFT -ohjaimen asianmukainen kohdistus kokoamisen aikana *kuvan 5B* mukaisesti.

GYNECARE PROLIFT -kanyylin sijoittaminen potilaaseen ***(kuvat 6A, 6B ja 6C)***



Kuva 6A *Kuva 6B* *Kuva 6C*

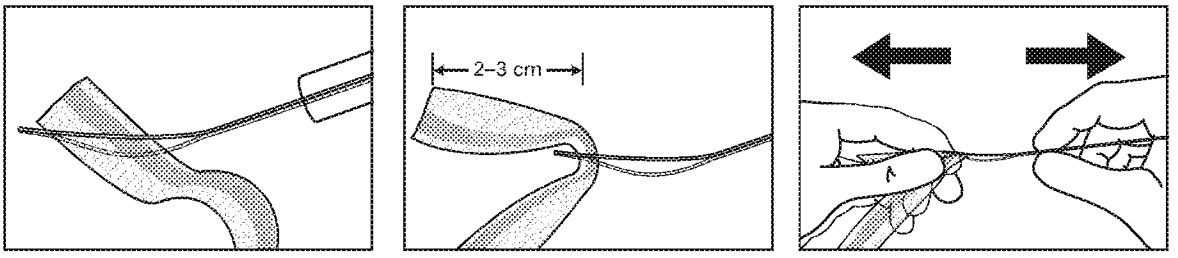
GYNECARE PROLIFT -noutosilmukan sisäänvienti ja reititys GYNECARE PROLIFT -kanyyliin ***(kuvat 7A ja 7B)***



Kuva 7A *Kuva 7B*

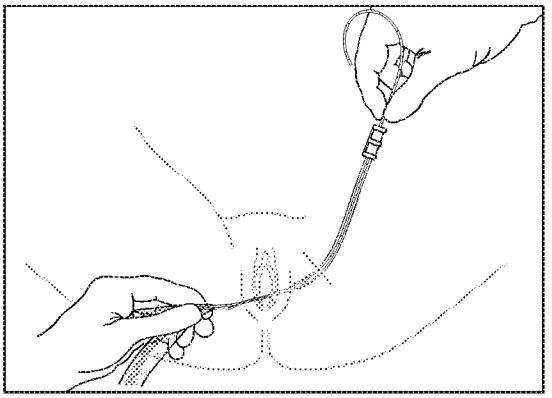
TÄRKEÄÄ: Kaikki pakkauksen mukana olevat GYNECARE PROLIFT -kanyylit ja GYNECARE PROLIFT -noutosilmukat on sijoitettava ennen verkkoimplantin asentamista.

Tartu verkkoimplanttinauhaan GYNECARE PROLIFT -noutosilmukalla ***(kuvat 8A, 8B ja 8C)***

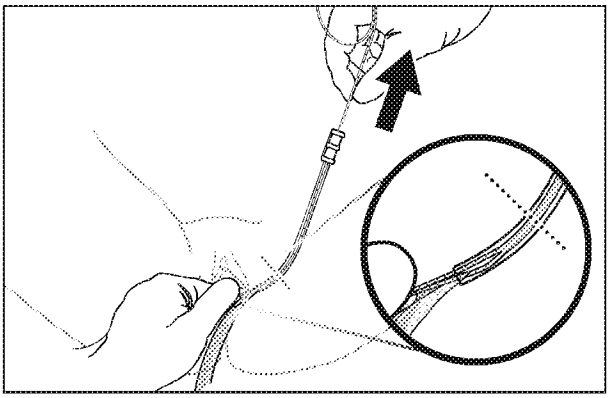


Kuva 8A *Kuva 8B* *Kuva 8C*

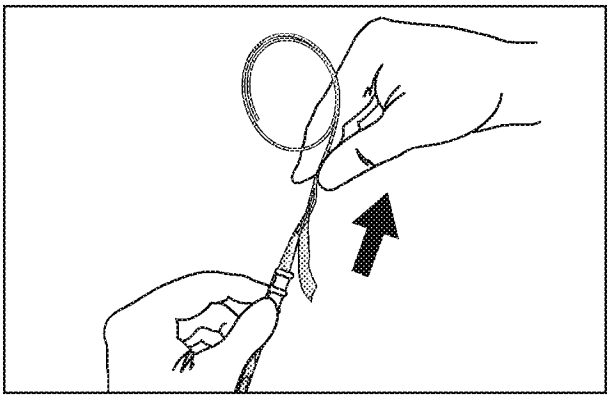
Verkkoimplanttinauhan reititys GYNECARE PROLIFT -kanyylin läpi *(kuvat 9A, 9B ja 9C)*



Kuva 9A



Kuva 9B



Kuva 9C

TÄRKEÄÄ: GYNECARE PROLIFT -kanyylia ei saa poistaa potilaasta ennen kuin verkkoimplantti on sijoitettu kunnolla paikoilleen.

Siinä tapauksessa, että ompeleita, hakasia tai muita kiinnityslaitteita käytetään verkon kanssa, suosittelemme että ne sijoitetaan vähintään 6,5 mm etäisyydelle verkon reunasta.

OMINAISUUDET

Eläimillä suoritetut kokeet osoittavat, että GYNECARE GYNEMESH PS -verkon implantointi aiheuttaa minimaalisen tai vähäisen tulehdusreaktion, joka on tilapäistä ja jonka jälkeen ohut, kuitumainen kudoskerros kiinnittyy verkkoon ja kasvaa verkon rakojen läpi, mikä yhdistää verkon viereiseen kudokseen. Verkko säilyy pehmeänä ja joustavana, eikä se haittaa näkyvästi normaalia haavan paranemisprosessia. Materiaali ei resorboidu, eikä se myöskään hajoa tai heikkene kudosentsyymien vaikutuksesta.

KONTRAINDIKAATIOT

Kun GYNECARE GYNEMESH PS -verkkoa käytetään vastasyntyneillä, vielä kasvavilla lapsilla, raskaana olevilla naisilla tai raskautta suunnittelevilla naisilla, kirurgin on otettava huomioon, ettei verkko veny merkittävästi potilaan kasvaessa.

VAROITUKSET JA VAROTOIMET

- Käyttäjän on tunnettava lantionpohjan korjauksia ja resorboitumattomia verkkoja koskevat toimenpiteet ja menetelmät ennen lantionpohjan GYNECARE PROLIFT -korjausjärjestelmien käyttöä.
- Tulehtuneiden tai kontaminoitujen haavojen hoidossa on noudatettava hyväksyttyjä kirurgisia toimenpiteitä.
- Leikkauksen jälkeen potilasta on neuvottava pidättäytymään yhdynnästä, raskaiden esineiden nostamisesta ja/tai liikunnasta (esim. pyöräily, hölkkä) kunnes lääkäri päättää milloin potilas voi palata normaaleihin toimintoihin.
- Vältä kiristämästä verkkoimplanttia liikaa käsittelyn aikana.
- Lisätietoja GYNECARE PROLIFT -toimenpiteistä ja suositelluista lantionpohjan GYNECARE PROLIFT -korjausjärjestelmistä on laitteen käyttöohjeissa.
- Lantionpohjan GYNECARE PROLIFT -korjausjärjestelmiä on käytettävä varovaisuutta noudattaen suonien, hermojen, virtsarakon ja suolien vaurioitumisen välttämiseksi. Riskit minimoidaan kiinnittämällä huomiota potilaan anatomiaan ja laitteen asianmukaiseen käyttöön.
- Ohimenevää kipua voi esiintyä alaraajoissa ja se voidaan normaalisti hallita kipulääkityksellä.
- GYNECARE PROLIFT -poistolaitetta ei saa käsitellä terävillä instrumenteilla tai leikata se pituuden muuttamiseksi.

KOMPLIKAATIOT

- Mahdollisia haittavaikutuksia ovat normaalit, kirurgisesti implantoitujen materiaalien yhteydessä havaitut haittavaikutukset, mukaan lukien infektion lisääntyminen, tulehdus, kiinnikkeiden muodostuminen, fisteleiden muodostuminen, eroosio, ulostyöntyminen ja arpeutumisesta aiheutuva implantin supistuminen.
- GYNECARE PROLIFT -ohjaimen sisäänviennin yhteydessä saattaa tapahtua kirurgista korjausta vaativia verisuonien, hermojen, virtsarakon tai suolen lävistyksiä tai repeämiä.

STERIILIYS

Lantionpohjan GYNECARE PROLIFT -korjausjärjestelmät on steriloitu etyleenioksidilla. EI SAA STERILOIDA UUDELLEEN. EI SAA KÄYTTÄÄ UUDELLEEN. Ei saa käyttää, jos pakkaus on avattu tai vaurioitunut. Hävitä avatut, käyttämättömät laitteet.

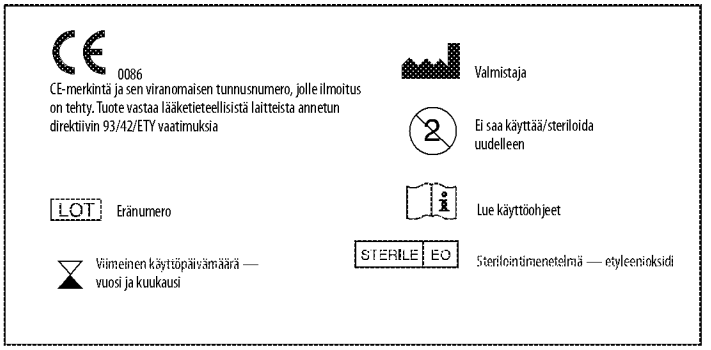
LAITTEEN JA TARVIKKEIDEN HÄVITTÄMINEN

Hävitä laitteet ja pakkausmateriaalit sairaalan biomateriaaleja ja -jätteitä koskevien ohjeiden mukaisesti.

SÄILYTYS

Suositeltavat säilytysolosuhteet: kontrolloitu huoneen lämpötila ja suhteellinen kohteus (noin 25 °C, 60 % suhteellinen kosteus), etäällä kosteudesta ja suorasta lämmöstä. Ei saa käyttää viimeisen käyttöpäivän jälkeen.

Tuotetarrojen symbolit



FRANÇAIS

Gynecare

PROLIFT*

Système pour cure de prolapsus total
Système pour cure de prolapsus antérieur
Système pour cure de prolapsus postérieur

Lire attentivement toutes les informations.
Le non-respect des instructions d'utilisation peut entraîner un dysfonctionnement des dispositifs médicaux et conduire à des lésions pour la patiente.

ATTENTION : La Loi Fédérale (États-Unis d'Amérique), n'autorise la vente de ce dispositif que par un médecin ou sur sa prescription.

Une formation relative à l'utilisation des systèmes pour cure de prolapsus GYNECARE PROLIFT* est recommandée. Il est possible de contacter le représentant de la Société afin d'obtenir des informations complémentaires.

Se reporter à la technique chirurgicale recommandée pour les systèmes pour cure de prolapsus GYNECARE PROLIFT afin d'obtenir plus d'informations sur les procédures GYNECARE PROLIFT.

INDICATIONS
Les systèmes pour cure de prolapsus GYNECARE PROLIFT sont indiqués pour le renforcement et la stabilisation à long terme des structures musculo-aponévrotiques du plancher pelvien lorsqu'une réparation chirurgicale de prolapsus génital est indiquée dans le but de créer un renfort mécanique ou pour couvrir les défauts musculo-aponévrotiques.

DESCRIPTION
Les systèmes pour cures de prolapsus antérieur, postérieur et total GYNECARE PROLIFT sont constitués de prothèses prédécoupées de treillis GYNECARE GYNEMESH* PS fait de PROLENE* non résorbable et d'un ensemble d'instruments facilitant la mise en place de ces prothèses. Le tableau suivant synthétise la composition de chaque système :

SYSTÈME POUR CURE DE PROLAPSUS	COMPOSANT			
	Prothèse	Guide	Dispositifs de récupération	Canules
Système pour cure de prolapsus total	1 prothèse totale	1	6	6
Système pour cure de prolapsus antérieur	1 prothèse antérieure	1	4	4
Système pour cure de prolapsus postérieur	1 prothèse postérieure	1	2	2

Tableau 1 – Composants des systèmes pour cures de prolapsus GYNECARE PROLIFT

GYNECARE GYNEMESH PS
Le treillis GYNECARE GYNEMESH PS est tricoté à partir de filaments de polypropylène extrudé dont la composition est identique à celle du fil de suture chirurgical non résorbable en polypropylène PROLENE, (ETHICON, INC.), conforme à la Pharmacopée des États-Unis d'Amérique (U.S.P.). Ce matériau, utilisé comme fil de suture, est signalé comme inerte et conserve sa résistance indéfiniment lors d'une utilisation clinique. Le treillis présente une résistance, une durabilité ainsi qu'une adaptabilité chirurgicale excellentes, avec une porosité suffisante pour permettre la colonisation tissulaire nécessaire. Des monofilaments de PROLENE Bleus ont été intégrés pour créer des stries de contraste dans le treillis. Le treillis est composé de fibres monofilamentaires de diamètre réduit, tricotées selon un modèle unique créant un treillis plus souple d'environ 50 pour cent que le treillis standard PROLENE. Le treillis est tricoté selon un procédé qui permet d'obtenir une maille interlock qui lui assure une extensibilité bidirectionnelle. Cette caractéristique permet de couper le treillis à la forme et aux dimensions souhaitées sans démaillage. Cette extensibilité bi-directionnelle permet au treillis de s'adapter aux différentes contraintes de l'organisme.

Prothèse totale
La prothèse totale est construite à partir d'un treillis GYNECARE GYNEMESH PS qui est découpé pour la réparation complète d'un prolapsus génital. La prothèse comprend 6 bras : 4 pour permettre la mise en place de la partie antérieure de la prothèse par voie trans-obturatrice et deux pour la mise en place de sa partie postérieure dans le ligament sacro-épineux par voie trans-glutéale. Alternativement, les deux bras postérieurs peuvent être raccourcis et fixés au ligament sacro-épineux par voie vaginale. Les bras antérieurs proximal et distal présentent respectivement des extrémités carrées et triangulaires, alors que les bras postérieurs présentent des extrémités arrondies *(voir la figure 1)*.

Prothèse antérieure

La prothèse antérieure est construite à partir d'un treillis GYNECARE GYNEMESH PS qui est découpé pour la réparation d'une cystocèle. La prothèse comprend 4 bras qui sont mis en place par voie trans-obturatrice. Les bras antérieurs proximal et distal présentent respectivement des extrémités carrées et triangulaires *(voir la figure 1)*.

Prothèse postérieure

La prothèse postérieure est construite à partir d'un treillis GYNECARE GYNEMESH PS qui est découpé pour la suspension du fond vaginal et/ou la réparation d'une élytrocèle et/ou rectocèle. La prothèse comprend deux bras qui sont passés dans le ligament sacro-épineux par voie trans-glutéale. Alternativement, les deux bras postérieurs peuvent être raccourcis et fixés au ligament sacro-épineux par voie vaginale. Les bras postérieurs présentent des extrémités arrondies *(voir la figure 1)*.

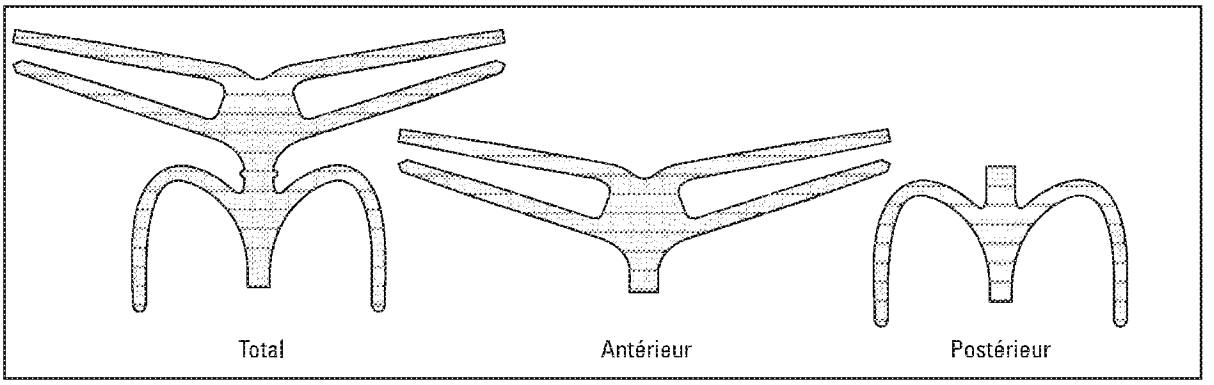


Figure 1 – Prothèse (totale, antérieure et postérieure)

Guide GYNECARE PROLIFT

Le guide GYNECARE PROLIFT est un instrument à usage unique conçu pour créer un passage à travers les tissus afin de permettre la mise en place des prothèses totale, antérieure et postérieure et de faciliter la mise en place de la canule GYNECARE PROLIFT. Sa longueur et sa courbure sont conçues tout particulièrement pour créer un passage adapté pour chaque bras de la prothèse. Le guide GYNECARE PROLIFT peut être utilisé indifféremment des deux côtés de la patiente *(voir la figure 2)*.

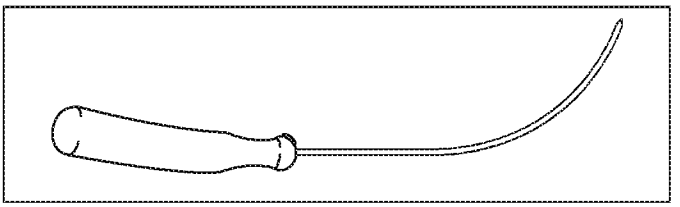


Figure 2 – Guide GYNECARE PROLIFT

Canule GYNECARE PROLIFT

La canule GYNECARE PROLIFT est un instrument à usage unique utilisé en même temps que le guide GYNECARE PROLIFT afin de faciliter le passage des bras de la prothèse tout en protégeant les tissus environnants. Chaque canule GYNECARE PROLIFT est placée sur le guide GYNECARE PROLIFT avant introduction et reste en place une fois le guide GYNECARE PROLIFT retiré *(voir la figure 3)*.

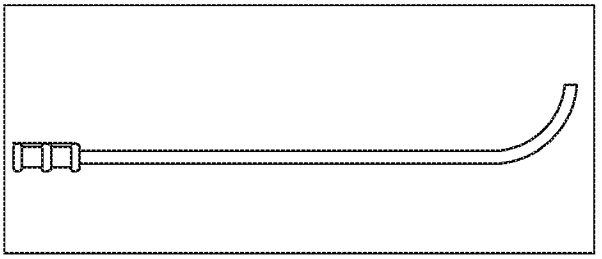


Figure 3 – Canule GYNECARE PROLIFT

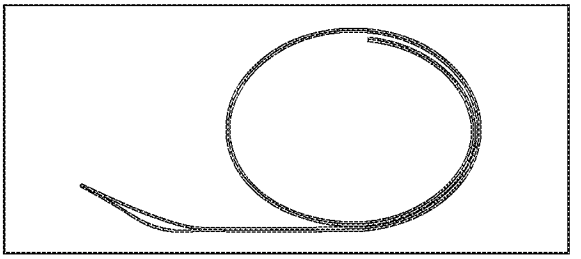


Figure 4 – Dispositif de récupération GYNECARE PROLIFT

Dispositif de récupération GYNECARE PROLIFT

Le dispositif de récupération GYNECARE PROLIFT est un instrument à usage unique conçu pour faciliter la mise en place des bras de la prothèse. Le dispositif de récupération GYNECARE PROLIFT s'insère à travers la canule GYNECARE PROLIFT préalablement mise en place jusqu'à ce que son extrémité distale puisse être récupérée à travers la dissection vaginale. L'extrémité distale du dispositif de récupération GYNECARE PROLIFT dispose d'une boucle qui permet de capturer solidement le bras de la prothèse pendant son retrait à travers la canule GYNECARE PROLIFT *(voir la figure 4)*.

MODE D'EMPLOI

REMARQUE : Toutes les figures présentées ci-dessous n'ont pas pour but de se substituer à un enseignement de la chirurgie mais uniquement d'illustrer l'utilisation générale de chaque dispositif.

Mise en place de la canule GYNECARE PROLIFT sur le guide GYNECARE PROLIFT *(voir les figures 5A et 5B).*

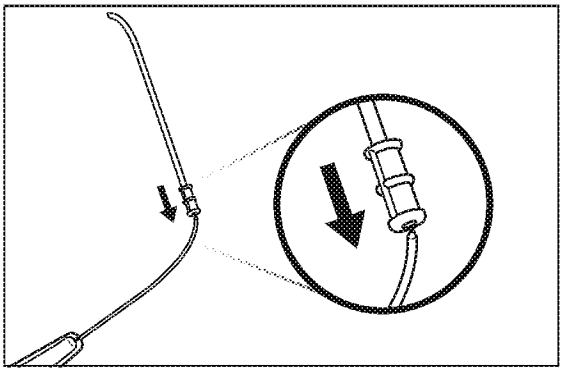


Figure 5A

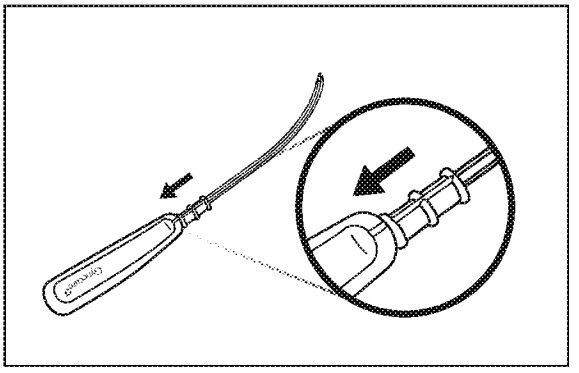


Figure 5B

IMPORTANT : Vérifier que l'alignement de la canule GYNECARE PROLIFT avec le guide GYNECARE PROLIFT est correct comme indiqué dans la *figure 5B*.

Mise en place de la canule GYNECARE PROLIFT sur la patiente *(voir les figures 6A, 6B et 6C).*

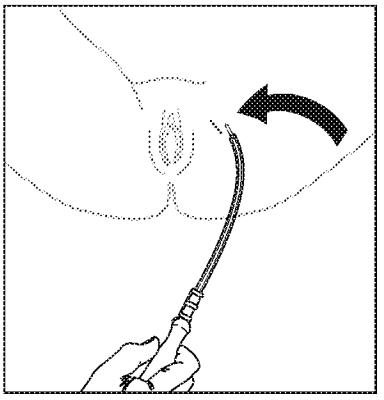


Figure 6A

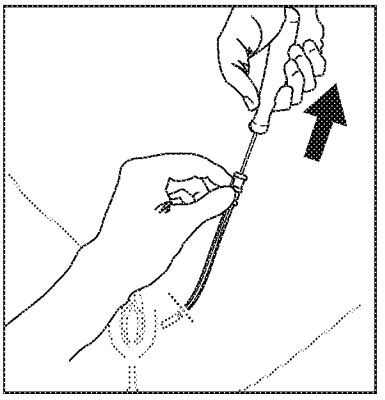


Figure 6B

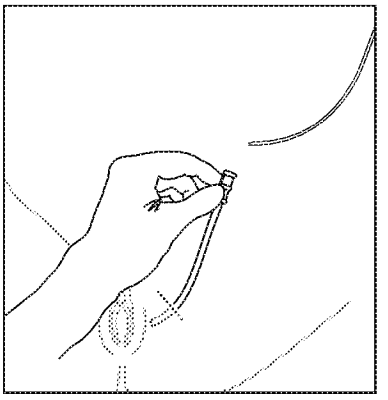


Figure 6C

Insertion et passage du dispositif de récupération GYNECARE PROLIFT dans la canule GYNECARE PROLIFT *(voir les figures 7A et 7B).*

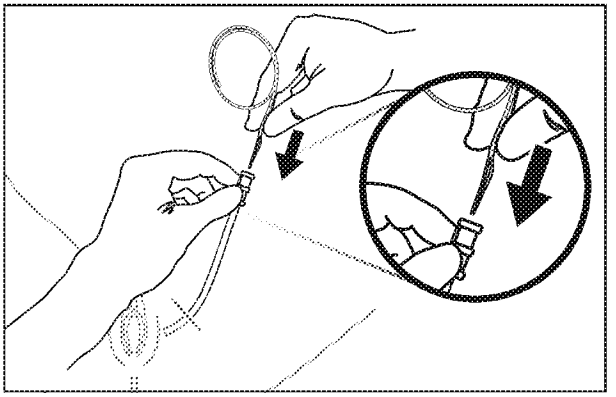


Figure 7A

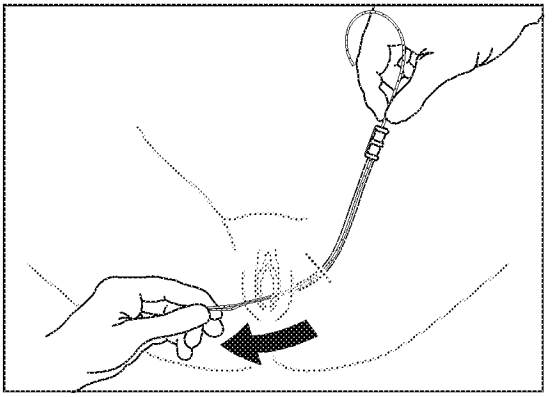


Figure 7B

IMPORTANT : Toutes canules GYNECARE PROLIFT et tous les dispositifs de récupération GYNECARE PROLIFT doivent être positionnés avant l'installation de la prothèse.

Capture d'un des bras de la prothèse avec le dispositif de récupération GYNECARE PROLIFT *(voir les figures 8A, 8B et 8C).*

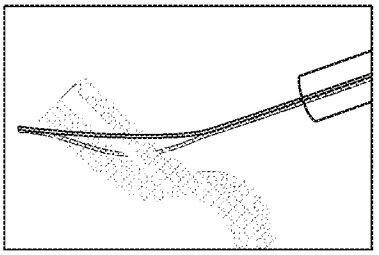


Figure 8A

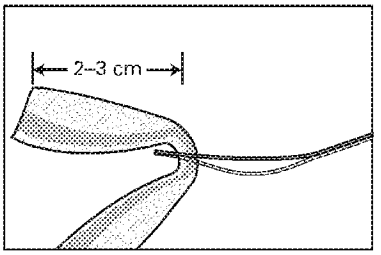


Figure 8B

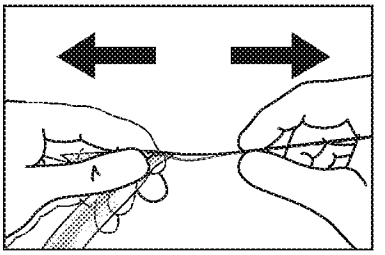


Figure 8C

Passage d'un des bras de la prothèse à travers la canule GYNECARE PROLIFT *(voir les figures 9A, 9B et 9C).*

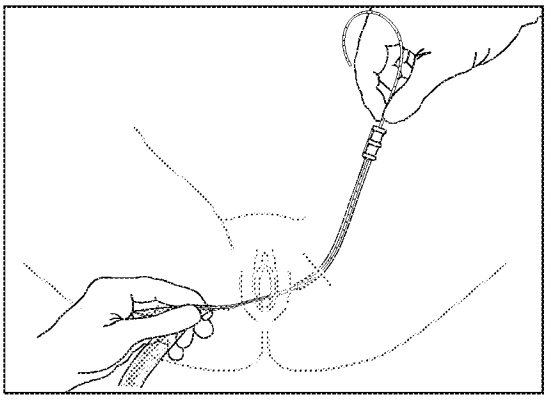


Figure 9A

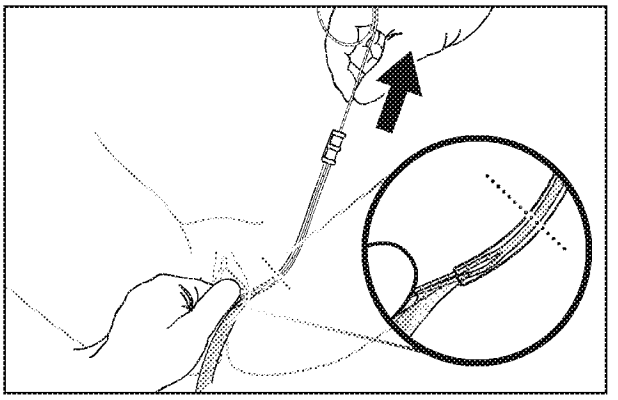


Figure 9B

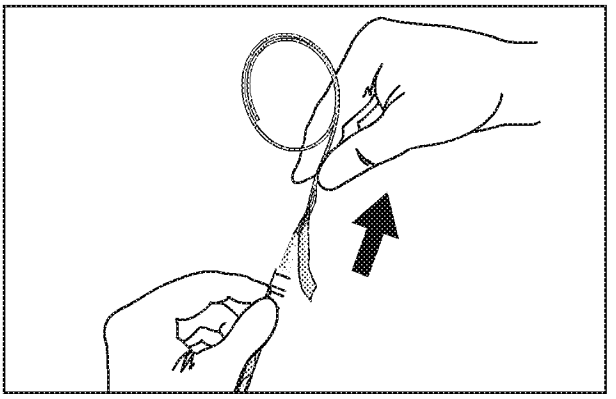


Figure 9C

IMPORTANT : Ne pas retirer les canules GYNECARE PROLIFT de la patiente tant que la prothèse n'a pas été correctement positionnée.

En cas d'utilisation de sutures, agrafes ou autres fixations en même temps que la prothèse, il est recommandé de les placer à 6,5 mm au moins du bord du treillis.

MODE D'ACTION

Des études réalisées sur l'animal ont montré que l'implantation du treillis GYNECARE GYNEMESH PS faisait apparaître une réaction inflammatoire minime à légère, qui est transitoire, et suivie d'une incorporation progressive du treillis par la fibrose consécutive à la colonisation des mailles du treillis. Le treillis reste souple et flexible, et la cicatrisation normale de la plaie n'est pas sensiblement affectée. Le matériau n'est pas résorbé ou dégradé ni fragilisé par l'action des enzymes tissulaires.

CONTRE-INDICATIONS

Lorsque le treillis GYNECARE GYNEMESH PS est utilisé chez le nourrisson, l'enfant, la femme enceinte ou désirant une grossesse, le chirurgien doit être averti que ce produit n'est pas suffisamment extensible pour accompagner la croissance du patient.

MISES EN GARDE ET PRÉCAUTIONS D'EMPLOI

- Avant d'employer les systèmes de réparation du plancher pelvien GYNECARE PROLIFT, l'utilisateur doit connaître les techniques et règles chirurgicales relatives à l'utilisation des treillis non résorbables pour la réparation du plancher pelvien.
- Des pratiques chirurgicales reconnues doivent être suivies en cas de plaies infectées ou contaminées.
- Après l'opération, la patiente doit être avertie qu'elle doit s'abstenir de tout rapport sexuel, éviter de soulever des charges lourdes et/ou de faire de l'exercice (par exemple, du vélo ou du jogging) tant que le médecin ne l'aura pas autorisée à reprendre une activité normale.
- Éviter d'appliquer une tension excessive sur la prothèse lors de sa manipulation.
- Se reporter à la technique chirurgicale recommandée pour l'utilisation des systèmes pour cure de prolapsus GYNECARE PROLIFT afin d'obtenir plus d'informations sur les procédures GYNECARE PROLIFT.
- Les systèmes pour cure de prolapsus GYNECARE PROLIFT doivent être utilisés avec précaution afin d'éviter d'endommager les vaisseaux, les nerfs, la vessie ou les intestins. Une prise en compte de l'anatomie propre à chaque patiente et le respect de la procédure de mise en place du dispositif permettra de minimiser les risques.
- Des douleurs passagères dans les jambes sont possibles et peuvent normalement être traitées avec de faibles doses d'analgésiques.
- Ne pas manipuler le dispositif de récupération GYNECARE PROLIFT avec des instruments coupants et ne pas le couper pour le raccourcir.

EFFETS INDÉSIRABLES

- Les réactions indésirables potentielles sont celles généralement lors de l'implantation de biomatériaux, en particulier une augmentation des risques infectieux, une réaction inflammatoire, la formation d'adhérences, la survenue de fistule ou d'érosion, la possibilité d'extrusion et de cicatrisation entraînant une rétraction de la prothèse.
- Des plaies ou lacérations des vaisseaux, des nerfs, de la vessie, de l'urètre ou de l'intestin peuvent se produire lors du passage du guide GYNECARE PROLIFT et entraîner la nécessité d'une réparation chirurgicale.

STÉRILITÉ

Les systèmes pour cures de prolapsus GYNECARE PROLIFT sont stérilisés à l'oxyde d'éthylène. NE PAS RESTÉRILISER. NE PAS RÉUTILISER. Ne pas utiliser si le protecteur de stérilité a été ouvert ou détérioré. Jeter tous les dispositifs non utilisés si l'emballage a été ouvert.

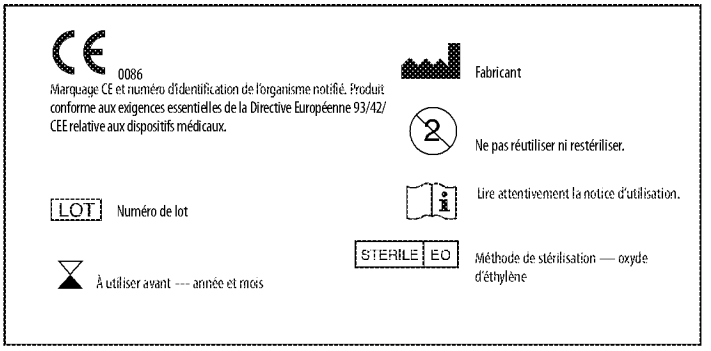
ÉLIMINATION

Éliminer les dispositifs et emballages conformément aux règles et procédures de votre établissement relatives aux matériaux et déchets présentant un danger biologique.

CONSERVATION

Conditions de stockage recommandées : température ambiante et humidité relative contrôlées (environ 25 °C, 60 % d'humidité relative), loin de toute source de chaleur directe et d'humidité. Ne pas utiliser au-delà de la date de péremption.

Symboles utilisés sur les étiquettes



DEUTSCH

Gynecare

PROLIFT*

Totalprolaps-Beckenboden-Rekonstruktionssystem
Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem

Bitte alle Informationen sorgfältig durchlesen.

Ein Nichtbeachten der Gebrauchsanweisung kann zu einer Fehlfunktion der Instrumente und Implantate und Verletzungen führen.

ACHTUNG: Laut Gesetz ist der Verkauf dieses Produkts in den USA nur auf ärztliche Anordnung gestattet.

Eine Schulung über die Verwendung des GYNECARE PROLIFT* Beckenboden-Rekonstruktionssystems wird empfohlen und angeboten. Wenden Sie sich an den für Sie zuständigen Außendienstmitarbeiter, um diese Schulung zu vereinbaren.

Weitere Informationen über die GYNECARE PROLIFT Verfahren sind in den Anweisungen zur empfohlenen chirurgischen Technik für das GYNECARE PROLIFT Beckenboden-Rekonstruktionssystems enthalten.

INDIKATIONEN

Die GYNECARE PROLIFT Totalprolaps-, anterioren und posterioren Beckenboden-Rekonstruktionssysteme sind zur Gewebeverstärkung und langfristigen Stabilisierung von Faszienstrukturen des Beckenbodens bei chirurgischen Verfahren in der Vaginalwand indiziert, bei denen das Netz als mechanische Stütze oder Überbrückung für den Fasziendefekt vorgesehen ist.

BESCHREIBUNG

Die GYNECARE PROLIFT Totalprolaps-, anterioren und posterioren Beckenboden-Rekonstruktionssysteme bestehen aus vorgefertigten GYNECARE GYNEMESH* PS nicht-resorbierbaren, weichen PROLENE* Netzimplantaten und einem Instrumentensatz, der das Einbringen des Netzimplantats erleichtert. Die folgende Tabelle fasst die in jedem System enthaltenen Komponenten zusammen:

REKONSTRUKTIONSSYSTEM	KOMPONENTEN			
	Netzimplantat	Führung	Rückholinstrument	Kanülen
Total	1, Total	1	6	6
Anterior	1, anterior	1	4	4
Posterior	1, posterior	1	2	2

Tabelle 1 – Komponenten der GYNECARE PROLIFT Beckenboden-Rekonstruktionssysteme

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS ist ein Netz, das aus geflochtenen Fäden aus extrudiertem Polypropylen hergestellt wird und in der Zusammensetzung identisch mit dem Material ist, das für PROLENE Polypropylen-Nahtmaterial verwendet wird, ein nicht-resorbierbares, chirurgisches Nahtmaterial, U.S.P. (ETHICON, INC.). Erfahrungen haben gezeigt, dass dieses Material bei Verwendung als chirurgisches Nahtmaterial keinerlei Reaktionen hervorruft und seine Festigkeit bei klinischer Anwendung unbeschränkt erhalten bleibt. Das Netz bietet hohe Zugkraft und Haltbarkeit, ist chirurgisch vielseitig einsetzbar und ausreichend porös, um das notwendige Einwachsen von Gewebe zu ermöglichen. Blaue PROLENE Monofilamente wurden eingewebt, um Kontraststreifen im Netz darzustellen. Das Netz besteht aus monofilen Fäden mit geringem Durchmesser, die auf besondere Weise zu einem Netz geknüpft werden, das ca. 50 Prozent flexibler ist als ein normales PROLENE Netz. Das Netz ist so verknüpft, dass die Fadenverbindungen miteinander verkettet sind, so dass es bidirektional dehnbar ist. Durch diese Struktur kann das Netz in jede gewünschte Form und Größe geschnitten werden, ohne auszufransen. Die bidirektionale Elastizität ermöglicht die Adaptation an verschiedene Belastungssituationen im Körper.

Totalprolaps-Netzimplantat

Das Totalprolaps-Netzimplantat wird aus GYNECARE GYNEMESH PS hergestellt und ist speziell geformt, um einen Vaginalprolaps zu beheben. Das Implantat verfügt über 6 Halteschlaufen: 4 zur Sicherung des anterioren Teils des Implantats über einen transobturatorischen Zugang und zwei zur Sicherung des posterioren Teils des Implantats im sakrospinalen Ligament über einen transglutealen Zugang. Alternativ können die 2 posterioren Halteschlaufen gekürzt werden, um ihre Länge zu reduzieren, und über einen vaginalen Zugang im sakrospinalen Ligament gesichert werden. Die proximalen und distalen anterioren Halteschlaufen haben rechteckige bzw. dreieckige Enden, während die posterioren Schlaufen abgerundet sind *(siehe Abbildung 1)*.

Anteriores Netzimplantat
Das anteriore Netzimplantat wird aus GYNECARE GYNEMESH PS hergestellt und ist für eine Rekonstruktion anteriorer vaginaler Defekte geformt. Das Implantat verfügt über 4 Halteschlaufen, die über einen transobturatorischen Zugang gesichert werden. Die proximalen und distalen anterioren Halteschlaufen haben rechteckige bzw. dreieckige Enden *(siehe Abbildung 1)*.

Posteriores Netzimplantat
Das posteriore Netzimplantat wird aus GYNECARE GYNEMESH PS hergestellt und ist für eine Rekonstruktion posteriorer und/oder apikaler Defekte des Scheidengewölbes geformt. Das Implantat verfügt über 2 Halteschlaufen, die über einen transglutealen Zugang im sakrospinalen Ligament gesichert werden. Alternativ können die 2 posterioren Halteschlaufen gekürzt werden, um ihre Länge zu reduzieren, und über einen vaginalen Zugang im sakrospinalen Ligament gesichert werden. Die posterioren Schlaufen haben abgerundete Enden *(siehe Abbildung 1)*.

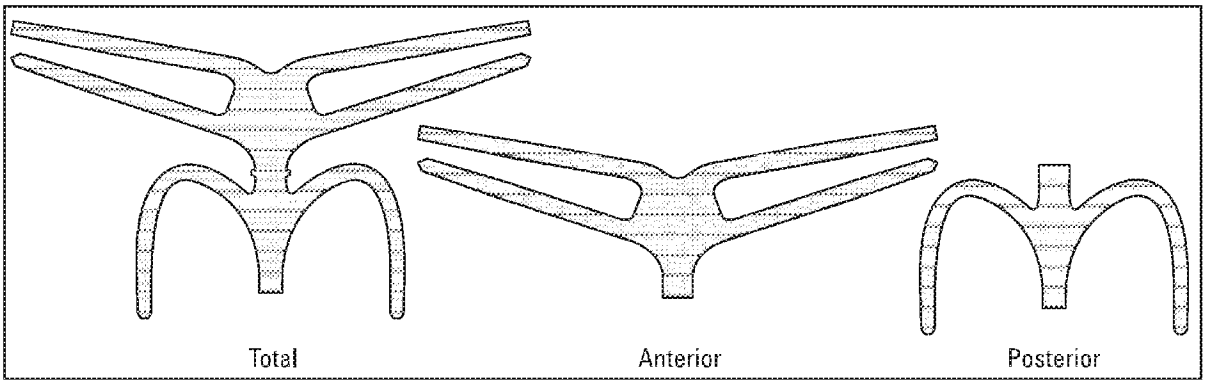


Abbildung 1 – Netzimplantate (Total, anterior und posterior)

GYNECARE PROLIFT Führung
Die GYNECARE PROLIFT Führung ist ein Einmalinstrument und dient zur Erstellung der Gewebepassage, um das Einbringen des Total-, anterioren oder posterioren Netzimplantats zu ermöglichen und die Einführung der GYNECARE PROLIFT Kanüle zu erleichtern. Seine Länge und Krümmung wurden speziell gestaltet, um geeignete Passagen für das Einführen der Halteschlaufen der Netzimplantate zu erstellen. Die GYNECARE PROLIFT Führung ist zur Verwendung auf beiden Seiten der Patientin geeignet *(siehe Abbildung 2)*.

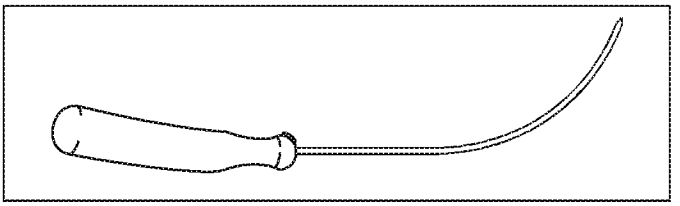


Abbildung 2 – GYNECARE PROLIFT Führung

GYNECARE PROLIFT Kanüle
Die GYNECARE PROLIFT Kanüle ist ein Einmalinstrument, das in Verbindung mit der GYNECARE PROLIFT Führung verwendet wird, um das Einbringen der Netzimplantatschlaufen bei gleichzeitigem Schutz des umgebenden Gewebes zu erleichtern. Jede GYNECARE PROLIFT Kanüle wird vor der Einbringung in das Gewebe über die GYNECARE PROLIFT Führung geschoben und verbleibt in situ, nachdem die GYNECARE PROLIFT Führung entfernt wurde *(siehe Abbildung 3)*.

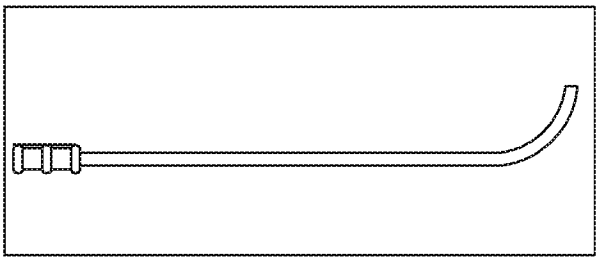


Abbildung 3 – GYNECARE PROLIFT Kanüle

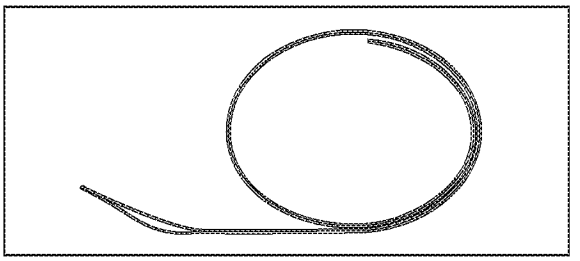


Abbildung 4 – GYNECARE PROLIFT Rückholinstrument

GYNECARE PROLIFT Rückholinstrument
Das GYNECARE PROLIFT Rückholinstrument ist für den Einmalgebrauch bestimmt und dient zur leichteren Positionierung der Halteschlaufen des Netzimplantats. Das GYNECARE PROLIFT Rückholinstrument wird durch die zuvor positionierte GYNECARE PROLIFT Kanüle geschoben, bis sein distales Ende durch die vaginale Inzision wieder erscheint. Das distale Ende des GYNECARE PROLIFT Rückholinstruments verfügt über eine Schlinge, um die Halteschlaufen des Netzimplantats sicher zu fassen, während das Implantat durch die GYNECARE PROLIFT Kanüle hindurch herausgezogen wird *(siehe Abbildung 4)*.

GEBRAUCHSINFORMATION

HINWEIS: Alle nachfolgenden Abbildungen sind nicht dazu vorgesehen, klinische Techniken zu vermitteln, sondern demonstrieren nur die allgemeine Anwendung der Instrumente.

Aufsetzen der GYNECARE PROLIFT Kanüle auf die GYNECARE PROLIFT Führung *(siehe Abbildungen 5A und 5B)*

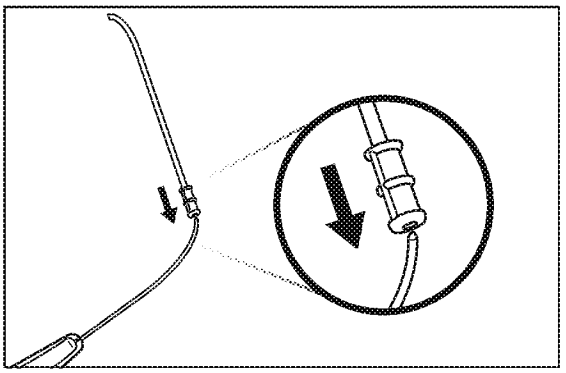


Abbildung 5A

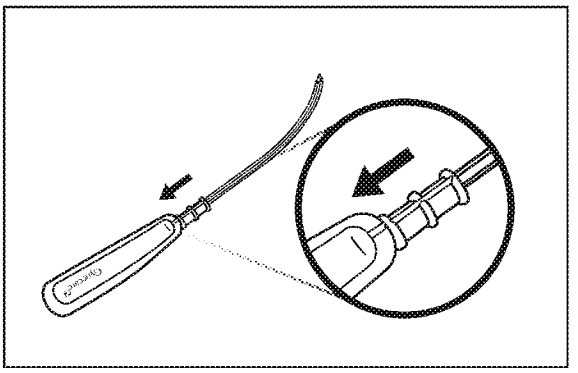


Abbildung 5B

WICHTIG: Die GYNECARE PROLIFT Kanüle und die GYNECARE PROLIFT Führung müssen beim Zusammensetzen korrekt ausgerichtet sein, wie in *Abbildung 5B* gezeigt

Einführen der GYNECARE PROLIFT Kanüle in die Patientin ***(siehe Abbildungen 6A, 6B und 6C)***

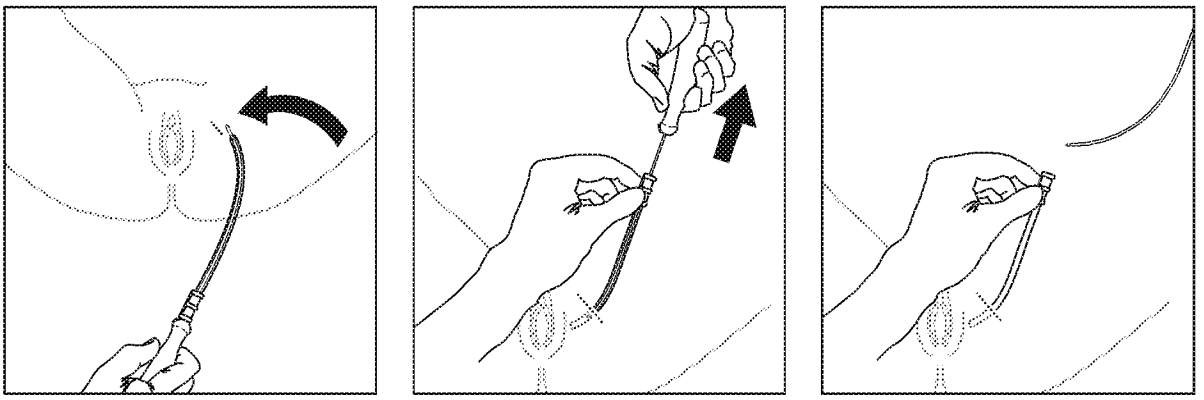


Abbildung 6A ***Abbildung 6B*** ***Abbildung 6C***

Einführen und Durchführen des GYNECARE PROLIFT Rückholinstruments durch die GYNECARE PROLIFT Kanüle ***(siehe Abbildungen 7A und 7B)***

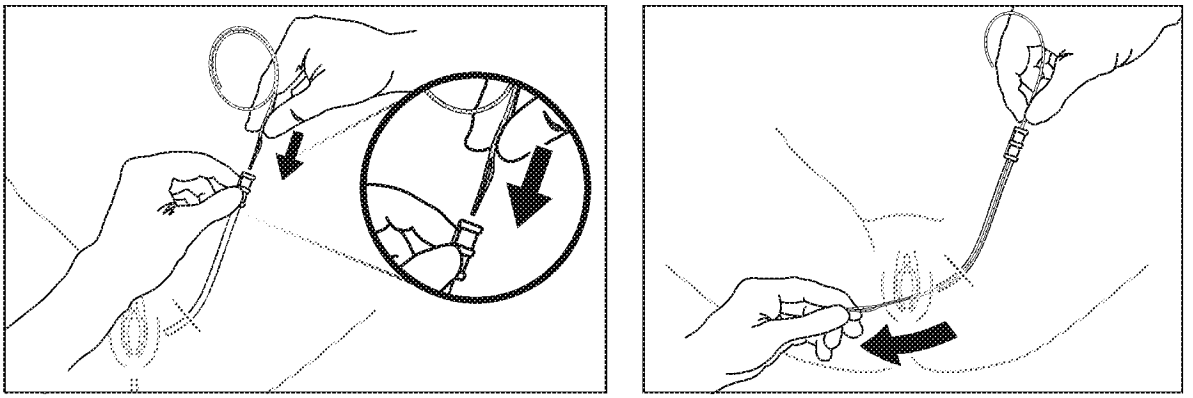


Abbildung 7A ***Abbildung 7B***

WICHTIG: Die mitgelieferten GYNECARE PROLIFT Kanülen und GYNECARE PROLIFT Rückholinstrumente müssen vor dem Einsetzen des Netzimplantats positioniert werden.

Fassen einer Halteschlaufe des Netzimplantats mit dem GYNECARE PROLIFT Rückholinstrument ***(siehe Abbildungen 8A, 8B und 8C)***

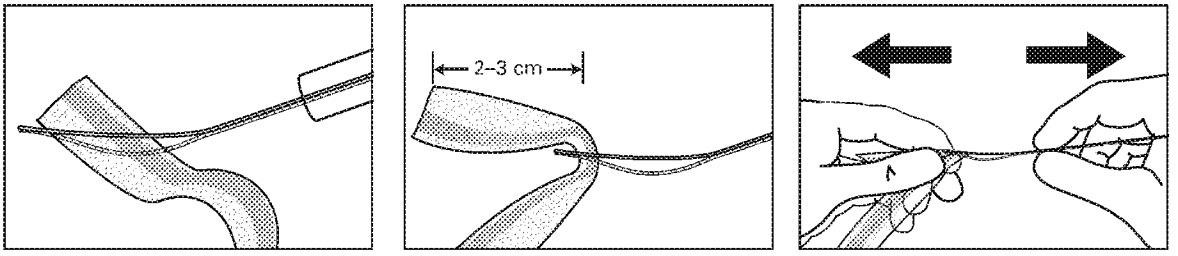


Abbildung 8A ***Abbildung 8B*** ***Abbildung 8C***

Durchführen einer Netzimplantat-Halteschlaufe durch die GYNECARE PROLIFT Kanüle ***(siehe Abbildungen 9A, 9B und 9C)***

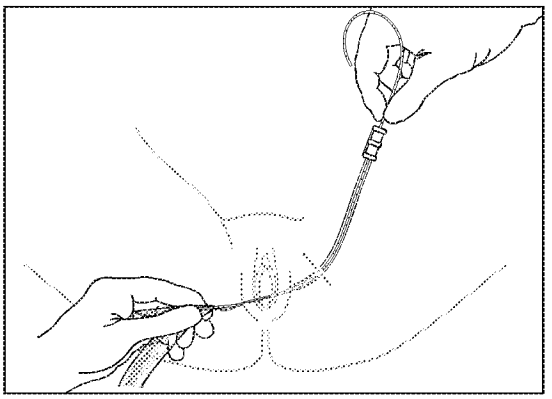


Abbildung 9A

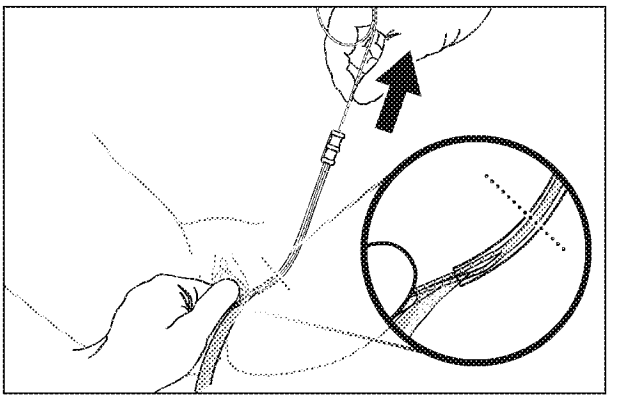


Abbildung 9B

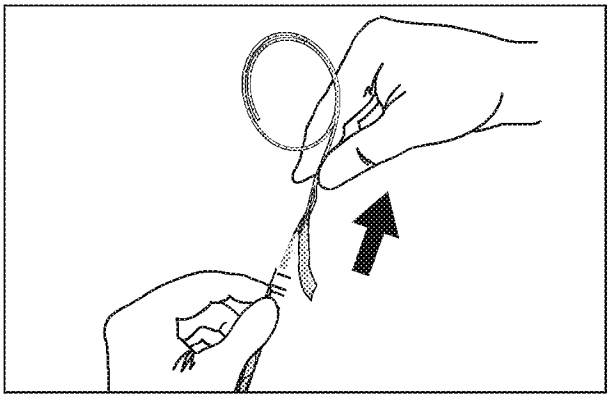


Abbildung 9C

WICHTIG: Die GYNECARE PROLIFT Kanülen dürfen erst aus dem Gewebe der Patientin entfernt werden, nachdem das Netzimplantat korrekt positioniert wurde.

Es wird empfohlen, eventuell verwendetes Nahtmaterial, Klammern und andere Fixierungshilfen mindestens 6,5 mm vom Rand des Netzes anzubringen.

WIRKUNGSWEISE

Tierversuche haben gezeigt, dass die Implantation von GYNECARE GYNEMESH PS Netz vorübergehend minimale bis leichte entzündliche Reaktionen hervorruft, gefolgt von der Ablagerung einer dünnen, fibrösen Gewebeschicht, welche die Zwischenräume des Geflechts durchdringen kann, wodurch das Netz mit dem anliegenden Gewebe verwächst. Das Netz bleibt weich und formbar, und die normale Wundheilung wird kaum beeinträchtigt. Das Material wird weder resorbiert noch durch Gewebeenzyme abgebaut oder geschwächt.

KONTRAINDIKATIONEN

Wenn GYNECARE GYNEMESH PS Netz bei Kleinkindern, Kindern, schwangeren Frauen oder Frauen mit Kinderwunsch verwendet wird, sollte der Arzt bedenken, dass das Netz nicht sehr dehnbar ist und sich dem Wachstum der Patientin nicht anpassen kann.

WARNUNGEN UND VORSICHTSMASSNAHMEN

- Der Chirurg sollte mit den entsprechenden Verfahren und Techniken zur Beckenbodenrekonstruktion mit nicht-resorbierbaren Netzimplantaten vertraut sein, bevor die GYNECARE PROLIFT Beckenboden-Rekonstruktionssysteme eingesetzt werden.
- Sollten infizierte oder kontaminierte Wunden vorliegen, so sind diese mit anerkannten chirurgischen Verfahren zu behandeln.
- Postoperativ sollte die Patientin angehalten werden, Geschlechtsverkehr, das Heben schwerer Gegenstände und/oder körperliches Training (z.B. Radfahren, Jogging) zu vermeiden, bis zu dem vom Arzt als geeignet festgestellten Zeitpunkt, ab dem die Patientin ihre normalen Aktivitäten wieder aufnehmen kann.
- Übermäßige Zugspannung auf das Netzimplantat während der Handhabung vermeiden.
- Weitere Informationen über die GYNECARE PROLIFT Verfahren sind in den Anweisungen zur empfohlenen chirurgischen Technik für das GYNECARE PROLIFT Beckenboden-Rekonstruktionssystem enthalten.
- Bei der Verwendung der GYNECARE PROLIFT Beckenboden-Rekonstruktionssysteme ist unbedingt darauf zu achten, dass Schäden an Gefäßen, Nerven, Blase und Darm vermieden werden. Durch Beachtung der Anatomie der Patientin und korrekte Verwendung des Produkts werden Risiken minimiert.
- Es können vorübergehende Schmerzen in den Beinen auftreten, die normalerweise durch Verabreichung schwacher Analgetika gelindert werden können.
- Das GYNECARE PROLIFT Rückholinstrument nicht mit scharfen Instrumenten manipulieren oder abschneiden, um die Länge zu ändern.

NEBENWIRKUNGEN

- Zu den möglichen Nebenwirkungen gehören die typischerweise mit chirurgischem Implantatmaterial verbundenen Reaktionen, wie erhöhte Infektionsgefahr, Entzündung, Verwachsungen, Fistelbildung, Erosion, Extrusion und Narbenbildung, die zu einer Kontraktion des Implantats führt.
- Bei der Platzierung der GYNECARE PROLIFT Führung kann es zu Beschädigungen von Blutgefäßen, Nerven, Blase, Harnröhre oder Darm in Form von Einstichen oder Rissen kommen, die chirurgischer Behandlung bedürfen.

STERILITÄT

Die GYNECARE PROLIFT Beckenboden-Reparatursysteme werden mit Ethylenoxid sterilisiert. NICHT RESTERILISIEREN. NICHT WIEDERVERWENDEN. Nicht verwenden, wenn die Verpackung geöffnet oder beschädigt ist. Alle geöffneten, nicht verwendeten Instrumente entsorgen.

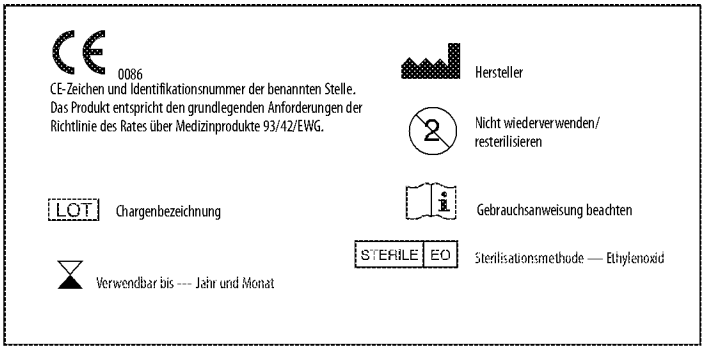
ENTSORGUNG

Die Entsorgung von Instrumenten und Verpackung hat unter Beachtung geltender Vorschriften für Gefahrenstoffe und Abfall zu erfolgen.

AUFBEWAHRUNG

Empfohlene Lagerbedingungen: kontrollierte Raumtemperatur und relative Luftfeuchtigkeit (ungefähr 25 °C, 60 % relative Luftfeuchtigkeit), geschützt vor Feuchtigkeit und direkter Hitzeeinwirkung. Nach Ablauf des Verfalldatums nicht mehr verwenden.

Etikettensymbole



ITALIANO

Gynecare

PROLIFT*

Sistema di riparazione totale del pavimento pelvico
Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico

Leggere attentamente le istruzioni.

La mancata osservanza di queste istruzioni può causare un funzionamento inadeguato dei dispositivi e provocare lesioni.

ATTENZIONE: la legge federale U.S.A. consente la vendita del prodotto solo dietro prescrizione medica.

L'addestramento all'uso dei sistemi per la riparazione del pavimento pelvico GYNECARE PROLIFT* è consigliato e disponibile. Per organizzare l'addestramento, contattare il promotore di zona.

Per ulteriori informazioni sulle procedure GYNECARE PROLIFT, fare riferimento alla tecnica chirurgica consigliata per i sistemi di riparazione del pavimento pelvico GYNECARE PROLIFT.

INDICAZIONI

I sistemi di riparazione totale, anteriore e posteriore del pavimento pelvico GYNECARE PROLIFT sono indicati per il rinforzo del tessuto e la stabilizzazione duratura delle strutture fasciali del pavimento pelvico nel prolasso della parete vaginale, in cui sono previsti trattamenti chirurgici, sia come supporto meccanico, sia come materiale di congiunzione per i difetti fasciali.

DESCRIZIONE

I sistemi di riparazione totale, anteriore e posteriore del pavimento pelvico GYNECARE PROLIFT sono costituiti da impianti in rete PROLENE* morbida non assorbibile GYNECARE GYNEMESH* PS pre-sagomata e da un set di strumenti per il posizionamento degli impianti in rete. Nella tabella seguente sono elencati gli strumenti contenuti in ciascun sistema:

SISTEMA DI RIPARAZIONE	COMPONENTI			
	Impianto in rete	Guida	Dispositivi di recupero	Cannule
Totale	1 totale	1	6	6
Anteriore	1 anteriore	1	4	4
Posteriore	1 posteriore	1	2	2

Tabella 1 – Componenti del sistema di riparazione del pavimento pelvico GYNECARE PROLIFT

GYNECARE GYNEMESH PS

GYNECARE GYNEMESH PS è una rete costituita da filamenti intrecciati di polipropilene estruso avente la stessa composizione delle suture chirurgiche non assorbibili in polipropilene PROLENE U.S.P. (ETHICON, INC.). Questo materiale, usato come sutura, è risultato non reattivo e, in applicazioni cliniche, ha dimostrato di mantenere la propria resistenza indefinitamente. La rete presenta caratteristiche di resistenza eccellente, durevolezza ed adattabilità come presidio chirurgico, con una porosità sufficiente alla necessaria crescita del tessuto. Nella rete sono stati incorporati dei monofilamenti blu di PROLENE allo scopo di produrre una rigatura di contrasto. La rete è costituita con fibre monofilamento a diametro ridotto, intrecciate secondo un modello esclusivo che genera una rete di circa il 50 percento più flessibile delle reti standard in PROLENE. La rete è lavorata con un processo che collega fra di loro le congiunzioni di ogni fibra e che conferisce elasticità in entrambe le direzioni. Questa struttura permette di tagliare la rete in qualunque forma o dimensione desiderata senza sfilarla. La proprietà di elasticità bidirezionale consente l'adattamento alle varie tensioni presenti nel corpo.

Impianto in rete totale

L'impianto in rete totale è costituito da GYNECARE GYNEMESH PS ed è pre-sagomato per l'esecuzione di una riparazione vaginale totale. L'impianto è dotato di 6 cinghie: 4 per fissare la parte anteriore dell'impianto tramite un sistema transotturatorio e due per il fissaggio della parte posteriore dell'impianto nel legamento sacrospinoso per via transgluteale. In alternativa, è possibile tagliare le 2 cinghie posteriori per ridurne la lunghezza e fissarle nel legamento sacrospinoso per via vaginale. Le cinghie anteriori prossimali e distali hanno rispettivamente estremità quadrate e triangolari, mentre le cinghie posteriori hanno estremità arrotondate *(vedere figura 1)*.

Impianto in rete anteriore

L'impianto in rete anteriore è costituito da GYNECARE GYNEMESH PS ed è pre-sagomato per l'esecuzione di una riparazione di difetti vaginali anteriori. L'impianto è dotato di 4 cinghie fissate tramite un sistema transotturatorio. Le cinghie anteriori prossimali e distali hanno rispettivamente estremità quadrate e triangolari *(vedere figura 1)*.

Impianto in rete posteriore

L'impianto in rete posteriore è costituito da GYNECARE GYNEMESH PS ed è pre-sagomato per l'esecuzione della riparazione di difetti della volta vaginale posteriore e/o apicale. L'impianto è dotato di 2 cinghie fissate al legamento sacrospinoso per via transgluteale. In alternativa, è possibile tagliare le 2 cinghie posteriori per ridurne la lunghezza e fissarle nel legamento sacrospinoso per via vaginale. Le cinghie posteriori hanno estremità arrotondate *(vedere figura 1)*.

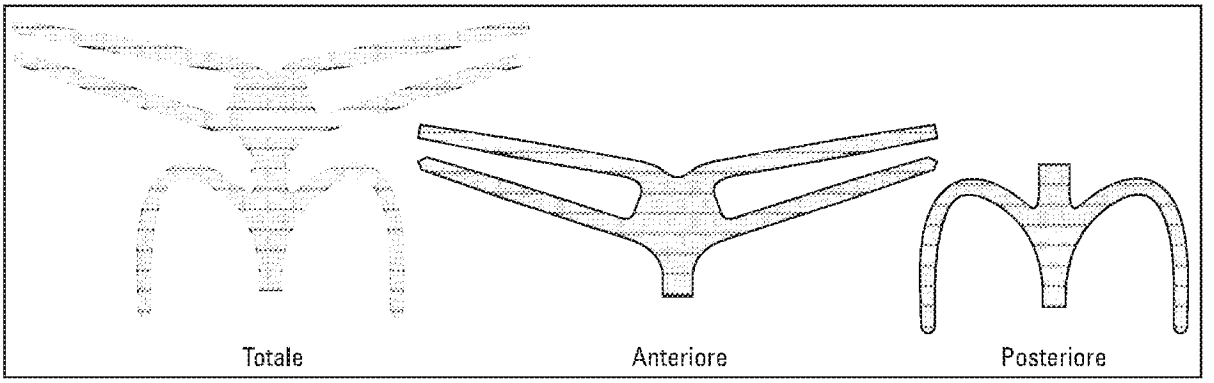


Figura 1 – Impianti in rete (totale, anteriore e posteriore)

Guida GYNECARE PROLIFT

La guida GYNECARE PROLIFT è uno strumento per l'utilizzo su una sola paziente, avente lo scopo di creare i percorsi di tessuto per consentire il posizionamento degli impianti in rete totale, anteriore e posteriore e per facilitare il posizionamento della cannula GYNECARE PROLIFT. La rispettiva lunghezza e curvatura sono appositamente studiate per creare percorsi adeguati per il posizionamento di tutte le cinghie dell'impianto in rete. La guida GYNECARE PROLIFT è adatta all'uso su entrambi i lati della paziente *(vedere figura 2)*.

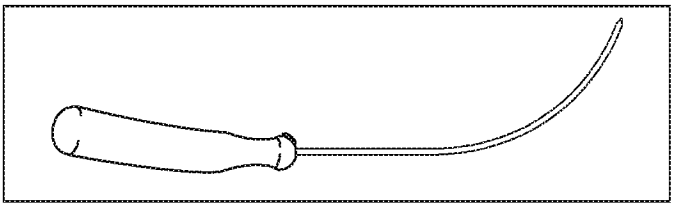


Figura 2 – Guida GYNECARE PROLIFT

Cannula GYNECARE PROLIFT

La cannula GYNECARE PROLIFT è uno strumento per l'utilizzo su una sola paziente, utilizzato in combinazione con la guida GYNECARE PROLIFT per facilitare il passaggio delle cinghie dell'impianto, proteggendo nel contempo il tessuto circostante. Ciascuna cannula GYNECARE PROLIFT viene posizionata sopra la guida GYNECARE PROLIFT prima del passaggio e rimane in posizione dopo il ritiro della guida GYNECARE PROLIFT *(vedere figura 3)*.

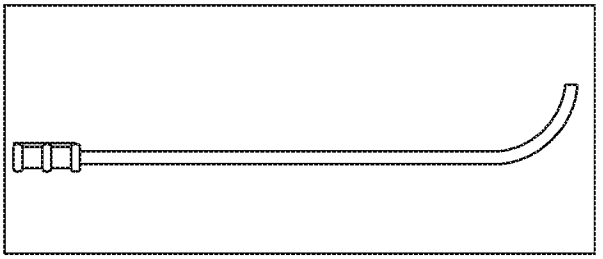


Figura 3 – Cannula GYNECARE PROLIFT

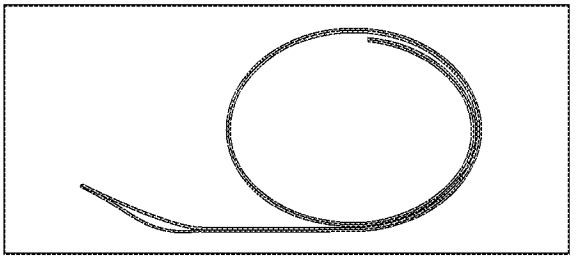


Figura 4 – Dispositivo di recupero GYNECARE PROLIFT

Dispositivo di recupero GYNECARE PROLIFT

Il dispositivo di recupero GYNECARE PROLIFT è uno strumento per l'utilizzo su una singola paziente, avente lo scopo di facilitare il posizionamento delle cinghie dell'impianto in rete. Il dispositivo di recupero GYNECARE PROLIFT viene fatto passare attraverso la cannula GYNECARE PROLIFT precedentemente posizionata fino a quando la sua estremità distale viene recuperata attraverso la dissezione vaginale. L'estremità distale del dispositivo di recupero GYNECARE PROLIFT è dotata di un anello per l'aggancio della cinghia dell'impianto in rete quando questa viene estratta dalla cannula GYNECARE PROLIFT *(vedere figura 4)*.

ISTRUZIONI PER L'USO

NOTA: le seguenti figure non vengono fornite a scopo di addestramento, ma solo per mostrare l'uso generico di ciascun dispositivo.

Posizionamento della cannula GYNECARE PROLIFT sulla guida GYNECARE PROLIFT *(vedere figure 5A e 5B)*

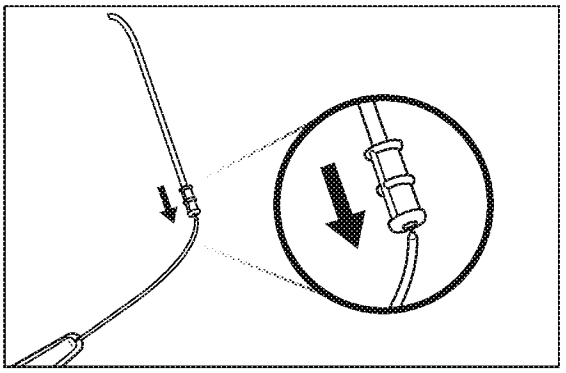


Figura 5A

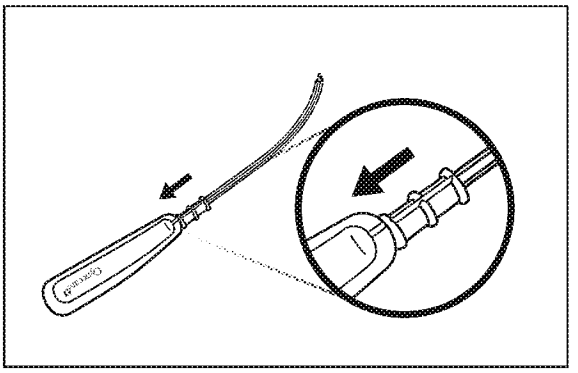


Figura 5B

IMPORTANTE: verificare il corretto allineamento della cannula GYNECARE PROLIFT e della guida GYNECARE PROLIFT al momento del montaggio come mostrato in *figura 5B*.

Posizionamento della cannula GYNECARE PROLIFT nella paziente *(vedere figure 6A, 6B e 6C)*

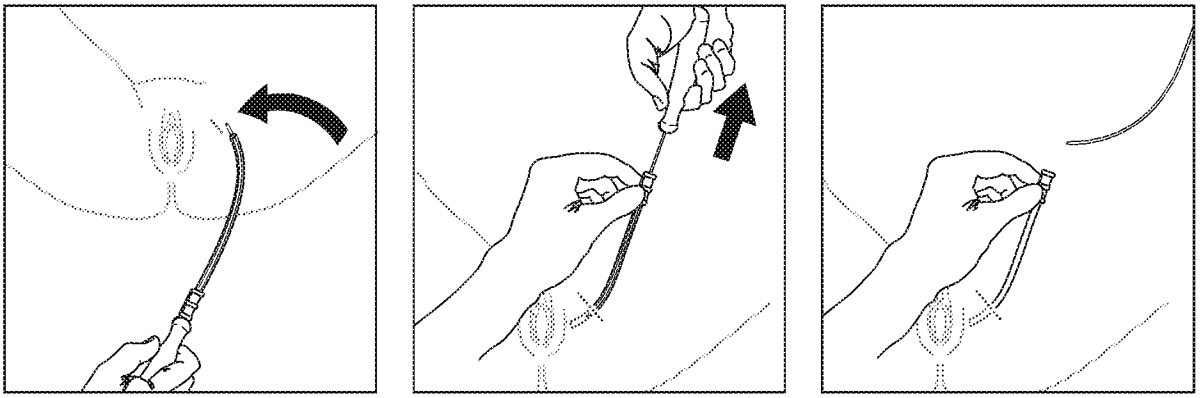


Figura 6A *Figura 6B* *Figura 6C*

Inserimento e passaggio del dispositivo di recupero GYNECARE PROLIFT nella cannula GYNECARE PROLIFT *(vedere figure 7A e 7B)*

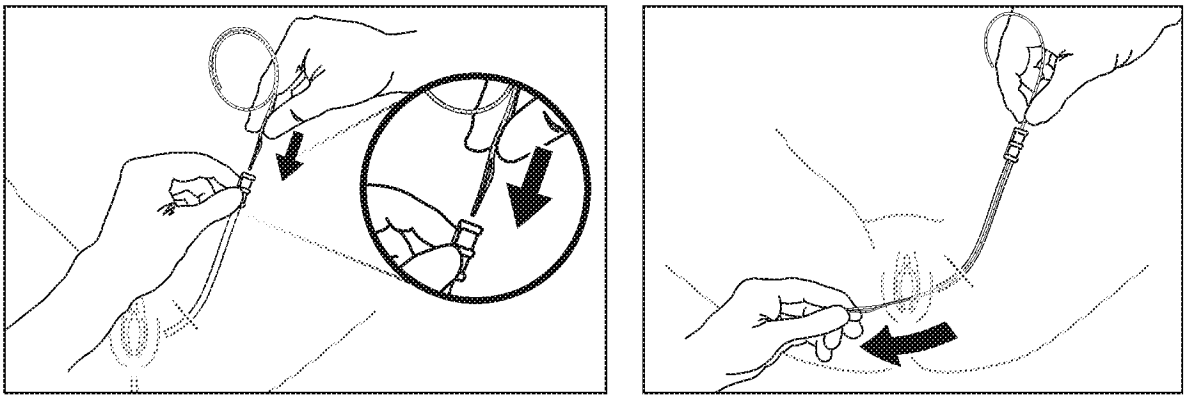


Figura 7A *Figura 7B*

IMPORTANTE: Tutte le cannule GYNECARE PROLIFT ed i dispositivi di recupero GYNECARE PROLIFT devono essere posizionati prima dell'installazione dell'impianto in rete.

Aggancio di una cinghia dell'impianto in rete con il dispositivo di recupero GYNECARE PROLIFT *(vedere figure 8A, 8B e 8C)*

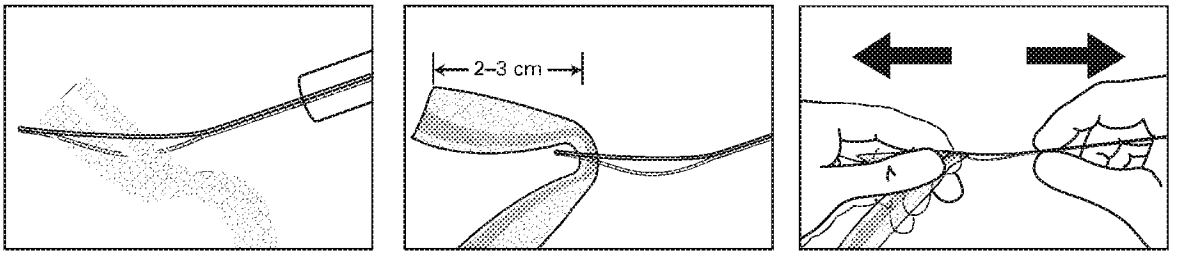


Figura 8A *Figura 8B* *Figura 8C*

Passaggio di una cinghia dell'impianto in rete attraverso la cannula GYNECARE PROLIFT *(vedere figure 9A, 9B e 9C)*

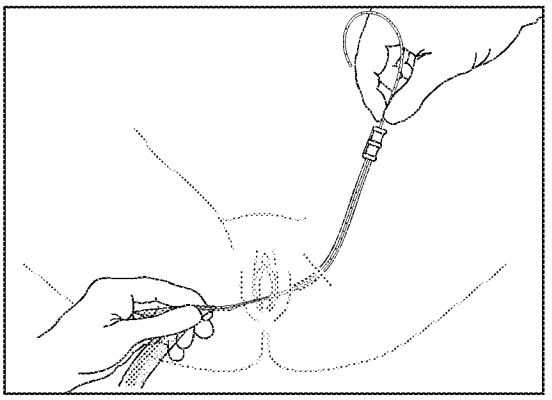


Figura 9A

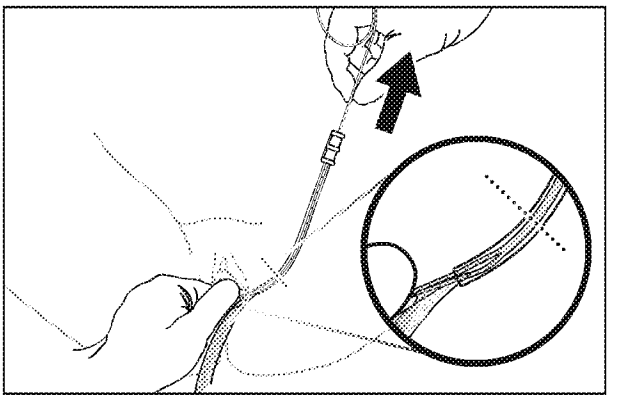


Figura 9B

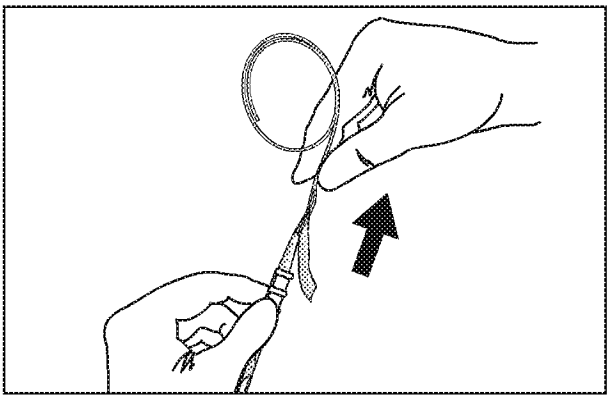


Figura 9C

IMPORTANTE: rimuovere le cannule GYNECARE PROLIFT dalla paziente solo dopo il corretto posizionamento degli impianti in rete.

Nel caso si utilizzino suture, punti o altri dispositivi di fissaggio insieme alla rete, si consiglia di posizionarli ad almeno 6,5 mm dal bordo della rete.

PRESTAZIONI

Studi su animali hanno mostrato che l'impianto della rete GYNECARE GYNEMESH PS causa una reazione infiammatoria minima o leggera, solo transitoria e seguita dalla deposizione di un sottile strato fibroso di tessuto in grado di crescere attraverso gli interstizi della rete, incorporando quindi la rete nel tessuto adiacente. La rete resta morbida e pieghevole e la normale guarigione della ferita non viene alterata. Il materiale non viene assorbito, né subisce degrado o indebolimento dall'azione degli enzimi tessutali.

CONTROINDICAZIONI

Quando la rete GYNECARE GYNEMESH PS viene usata in neonati, bambini, donne in gravidanza o donne che hanno intenzione di avere una futura gravidanza, il chirurgo deve essere consapevole che questo prodotto potrebbe non estendersi sufficientemente per la crescita della paziente.

AVVERTENZE E PRECAUZIONI

- Gli utilizzatori devono conoscere molto bene le procedure e le tecniche chirurgiche che riguardano la riparazione del pavimento pelvico e delle reti non assorbibili prima di usare i sistemi di riparazione del pavimento pelvico GYNEMESH PS GYNECARE.
- Attenersi a procedure chirurgiche riconosciute in presenza di ferite infette o contaminate.
- Dopo l'intervento, la paziente dovrà astenersi dall'avere rapporti sessuali, dal sollevare pesi e/o svolgere esercizio fisico (ad es. ciclismo, corsa) fino a quando il medico non stabilirà che la paziente può tornare alle normali attività.
- Durante la manipolazione, evitare di esercitare un'eccessiva tensione sull'impianto in rete.
- Per ulteriori informazioni sulle procedure GYNECARE PROLIFT, fare riferimento alla tecnica chirurgica consigliata per il sistema di riparazione del pavimento pelvico GYNECARE PROLIFT.
- I sistemi di riparazione del pavimento pelvico GYNECARE PROLIFT devono essere utilizzati con attenzione per evitare di danneggiare vasi, nervi, vescica e intestino. Per ridurre al minimo i rischi è importante conoscere l'anatomia della paziente ed effettuare un uso corretto del dispositivo.
- È possibile che si presenti un dolore transitorio alle gambe che di solito potrà essere risolto mediante analgesici leggeri.
- Evitare di manipolare il dispositivo di recupero GYNECARE PROLIFT con strumenti appuntiti o di tagliarlo per modificarne la lunghezza.

EFFETTI INDESIDERATI

- I potenziali effetti collaterali sono quelli di solito associati ai materiali impiantabili chirurgicamente, compresa una possibilità di infezione, infiammazione, formazione di aderenze, formazione di fistole, erosione, estrusione e cicatrizzazione con conseguente contrazione dell'impianto.
- Durante il passaggio della guida GYNECARE PROLIFT possono verificarsi perforazioni o lacerazioni di vasi, nervi, vescica, uretra o intestino, che potrebbero necessitare di una riparazione chirurgica.

STERILITÀ

I sistemi di riparazione del pavimento pelvico GYNECARE PROLIFT sono sterilizzati con ossido di etilene. NON RISTERILIZZARE. NON RIUTILIZZARE. Non usare se la confezione è stata aperta o danneggiata. Eliminare tutti i dispositivi aperti e non usati.

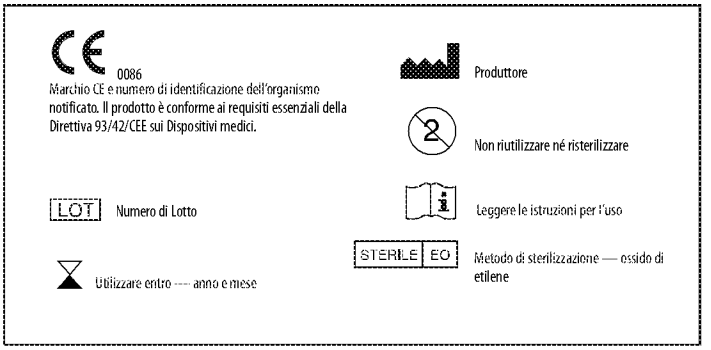
SMALTIMENTO

Smaltire i dispositivi e le confezioni conformemente alle politiche dell'azienda e alle procedure relative ai materiali e rifiuti a rischio biologico.

CONSERVAZIONE

Condizioni raccomandate per la conservazione: temperatura ambiente e umidità relativa controllate (circa 25 °C, 60 % di umidità relativa), al riparo da umidità e calore diretto. Non usare dopo la data di scadenza.

Simboli usati sulle etichette



PORTUGUÊS

Gynecare

PROLIFT*

Sistema de reparação do pavimento pélvico total
Sistema de reparação do pavimento pélvico anterior
Sistema de reparação do pavimento pélvico posterior

Leia atentamente todas as informações.
O não cumprimento das instruções poderá originar o funcionamento indevido dos dispositivos e provocar lesões pessoais.

ATENÇÃO: A lei federal (dos Estados Unidos da América) só permite a venda deste dispositivo a médicos ou sob receita destes.

Recomenda-se e encontra-se disponível formação relativa ao uso dos sistemas de reparação do pavimento pélvico GYNECARE PROLIFT*. Contacte o representante de vendas da sua empresa para providenciar esta formação.

Consulte a técnica cirúrgica recomendada para os sistemas de reparação do pavimento pélvico GYNECARE PROLIFT para obter mais informações sobre os procedimentos GYNECARE PROLIFT.

INDICAÇÕES
Os sistemas de reparação do pavimento pélvico total, anterior e posterior GYNECARE PROLIFT estão indicados para reforço do tecido e estabilização de longa duração de estruturas fasciais do pavimento pélvico no prolapso da parede vaginal com indicação de trata-mento cirúrgico, como suporte mecânico ou material de ligação para o defeito fascial.

DESCRIÇÃO
Os sistemas de reparação do pavimento pélvico total, anterior e posterior GYNECARE PROLIFT são constituídos por implantes de rede PROLENE* soft não absorvível GYNECARE GYNEMESH* PS pré-cortados e por um conjunto de instrumentos destinados a facilitar a colocação do implante de rede. No quadro seguinte resumem-se os instrumentos fornecidos com cada sistema:

SISTEMA DE REPARAÇÃO	COMPONENTES			
	Implante de rede	Guia	Dispositivos de recuperação	Cânulas
Total	1 total	1	6	6
Anterior	1 anterior	1	4	4
Posterior	1 posterior	1	2	2

Quadro 1 – Componentes dos sistemas de reparação do pavimento pélvico GYNECARE PROLIFT

GYNECARE GYNEMESH PS
A GYNECARE GYNEMESH PS é uma rede feita a partir de filamentos tecidos de polipropileno extrudido, idêntico em composição ao utilizado na sutura cirúrgica não absorvível de polipropileno PROLENE, U.S.P. (ETHICON, INC.). Este material, quando usado como sutura, demonstrou não ser reactivo e manter a sua resistência indefinidamente em uso clínico. A rede proporciona excelente resistência, durabilidade e adaptabilidade cirúrgica, com porosidade suficiente para o necessário crescimento interno do tecido. Os monofilamentos azuis PROLENE foram introduzidos para criar faixas de contraste na rede. A rede é constituída por fibras monofilamentares de diâmetro reduzido, tecidas de modo a formar um padrão exclusivo que confere a esta rede uma flexibilidade de cerca de 50 porcento superior à da rede PROLENE standard. A rede é tecida mediante um processo que entrelaça as uniões de cada fibra e que lhe confere elasticidade em ambas as direcções. Este processo de fabrico permite que a rede seja cortada em qualquer formato ou tamanho desejado, sem desfiar. A propriedade elástica bidireccional permite a adaptação às várias tensões encontradas no corpo.

Implante de rede total
O implante de rede total é construído a partir da GYNECARE GYNEMESH PS e a sua forma destina-se à realização de uma reparação vaginal total. O implante apresenta 6 tiras: 4 para fixação da zona anterior do implante através de uma abordagem transobturador e duas para fixação da zona posterior do implante no ligamento sacro-espinal através de uma abordagem transglútea. Em alternativa, as 2 tiras posteriores podem ser cortadas para reduzir o seu comprimento e fixas ao ligamento sacro-espinal através de uma abordagem vaginal. As tiras anteriores proximais e distais apresentam extremidades quadradas e triangulares, respectivamente, enquanto que as tiras posteriores apresentam extremidades arredondadas *(consulte a Figura 1)*.

Implante de rede anterior
O implante de rede anterior é construído a partir da GYNECARE GYNEMESH PS e a sua forma destina-se à reparação de defeitos vaginais anteriores. O implante apresenta 4 tiras que são fixas através de uma abordagem transobturador. As tiras anteriores proximais e distais apresentam extremidades quadradas e triangulares, respectivamente *(consulte a Figura 1)*.

Implante de rede posterior
O implante de rede posterior é construído a partir da GYNECARE GYNEMESH PS e a sua forma destina-se à reparação de defeitos vaginais posteriores e/ou da abóbada vaginal apical. O implante apresenta 2 tiras que são fixas no ligamento sacro-espinal através de uma abordagem transglútea. Em alternativa, as 2 tiras posteriores podem ser cortadas para reduzir o seu comprimento e fixas ao ligamento sacro-espinal através de uma abordagem vaginal. As tiras posteriores apresentam extremidades arredondadas *(consulte a Figura 1)*.

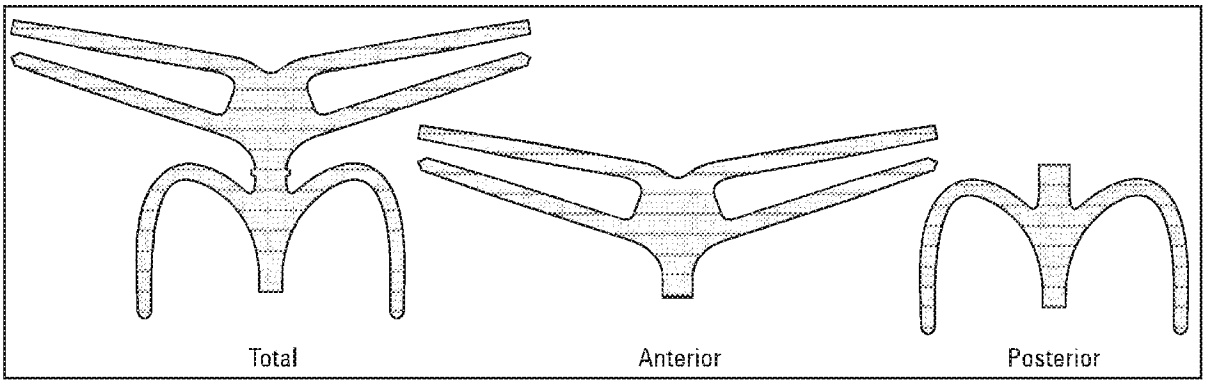


Figura 1 – Implantes de rede (total, anterior e posterior)

Guia GYNECARE PROLIFT
O guia GYNECARE PROLIFT consiste num instrumento destinado a ser utilizado numa única doente, concebido para criar vias nos tecidos para permitir a colocação dos implantes de rede anterior, posterior e total e facilitar a colocação da cânula GYNECARE PROLIFT. O seu comprimento e curvatura foram especificamente concebidos para criar vias de colocação adequadas para todas as tiras do implante de rede. O guia GYNECARE PROLIFT é adequado para utilização nos dois lados da doente *(consulte a Figura 2)*.

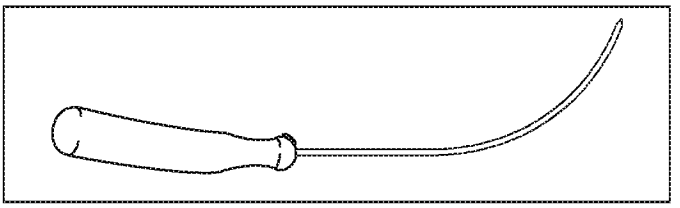


Figura 2 – Guia GYNECARE PROLIFT

Cânula GYNECARE PROLIFT

A cânula GYNECARE PROLIFT consiste num instrumento destinado a ser utilizado numa única doente, usado em conjunto com o guia GYNECARE PROLIFT para facilitar a passagem das tiras do implante e proteger simultaneamente os tecidos circundantes. Cada cânula GYNECARE PROLIFT é colocada sobre o guia GYNECARE PROLIFT antes da passagem e permanece colocada depois de se retirar o guia GYNECARE PROLIFT *(consulte a Figura 3)*.

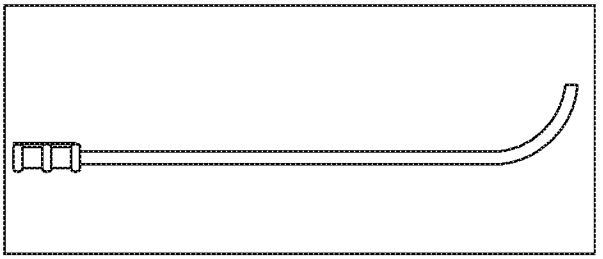


Figura 3 – Cânula GYNECARE PROLIFT

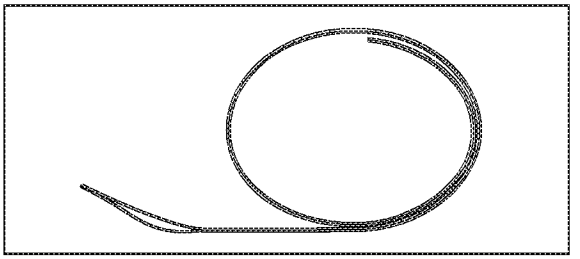


Figura 4 – Dispositivo de recuperação GYNECARE PROLIFT

Dispositivo de recuperação GYNECARE PROLIFT

O dispositivo de recuperação GYNECARE PROLIFT consiste num instrumento destinado a ser utilizado numa única doente, concebido para facilitar a colocação das tiras do implante de rede. O dispositivo de recuperação GYNECARE PROLIFT é passado através da cânula GYNECARE PROLIFT previamente posicionada, até a sua extremidade distal ser recuperada através da dissecção vaginal. A extremidade distal do dispositivo de recuperação GYNECARE PROLIFT dispõe de uma ansa para prender bem a tira do implante de rede à medida que a tira é puxada para fora, através da cânula GYNECARE PROLIFT *(consulte a Figura 4)*.

INSTRUÇÕES DE UTILIZAÇÃO

NOTA: Nenhuma das figuras apresentadas em baixo se destina a facultar qualquer formação clínica, tendo por exclusiva finalidade demonstrar a utilização genérica de cada dispositivo.

Colocação da cânula GYNECARE PROLIFT no guia GYNECARE PROLIFT *(consulte as Figuras 5A e 5B)*

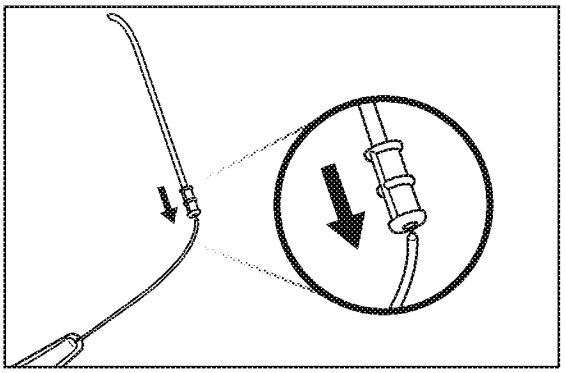


Figura 5A

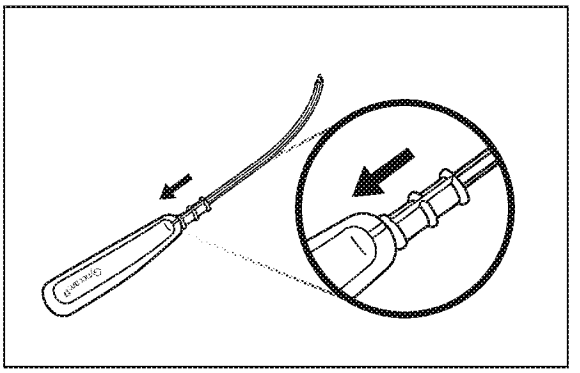


Figura 5B

IMPORTANTE: Assegure-se do alinhamento adequado do conjunto da cânula GYNECARE PROLIFT e guia GYNECARE PROLIFT, conforme demonstrado na *Figura 5B*.

Colocação da cânula GYNECARE PROLIFT na doente *(consulte as Figuras 6A, 6B e 6C)*

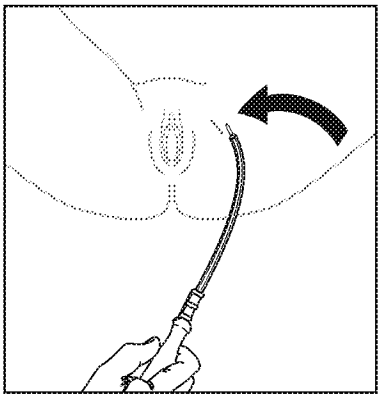


Figura 6A

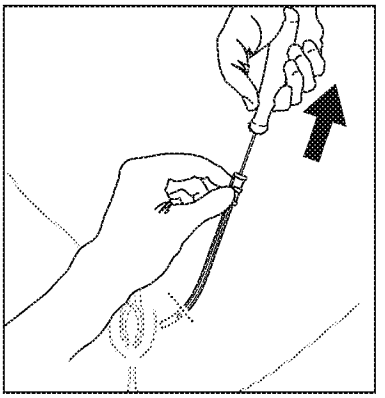


Figura 6B

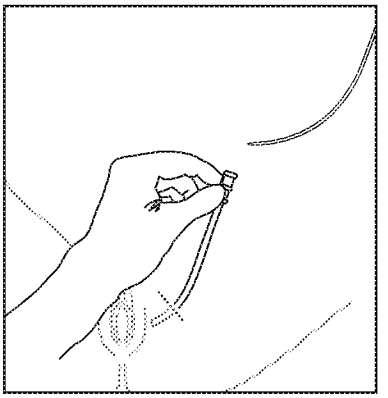


Figura 6C

Introdução e passagem do dispositivo de recuperação GYNECARE PROLIFT na cânula GYNECARE PROLIFT *(consulte as Figuras 7A e 7B)*

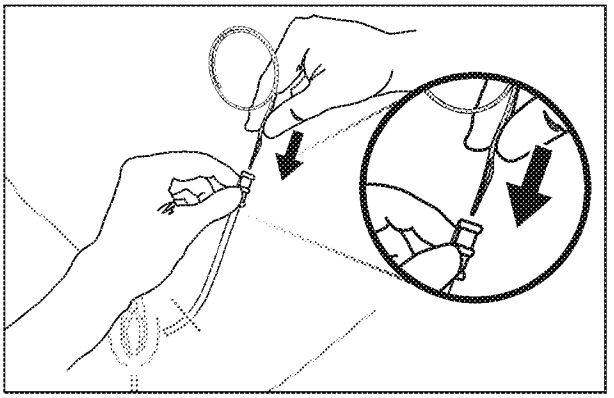


Figura 7A

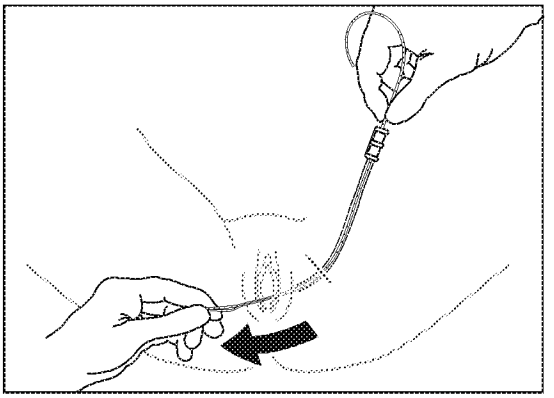


Figura 7B

IMPORTANTE: Todas as cânulas GYNECARE PROLIFT e os dispositivos de recuperação GYNECARE PROLIFT fornecidos deverão ser colocados antes da instalação do implante de rede.

Captura de uma tira do implante de rede com o dispositivo de recuperação GYNECARE PROLIFT *(consulte as Figuras 8A, 8B e 8C)*

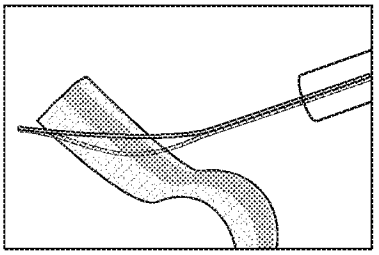


Figura 8A

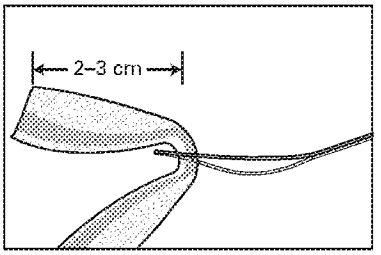


Figura 8B

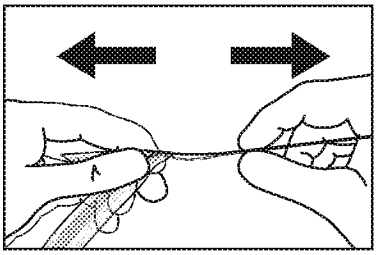


Figura 8C

Passagem de uma tira do implante de rede através da cânula GYNECARE PROLIFT *(consulte as Figuras 9A, 9B e 9C)*

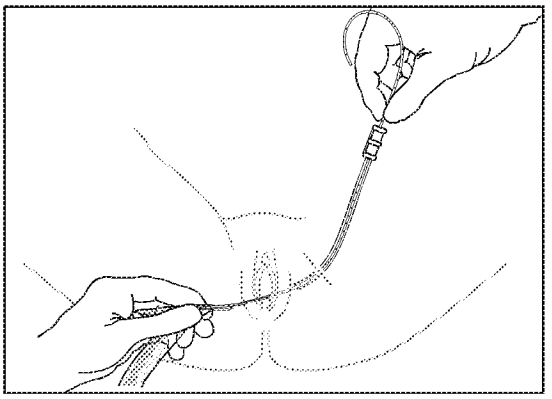


Figura 9A

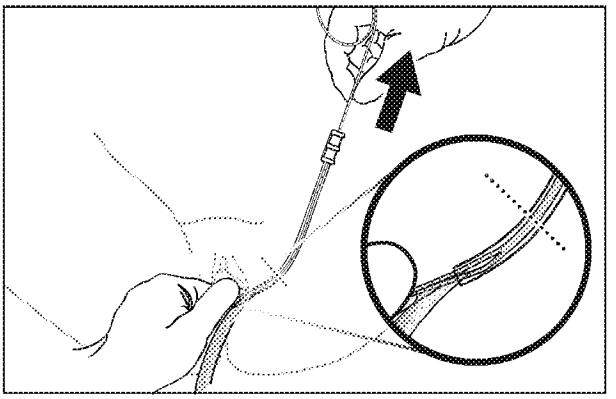


Figura 9B

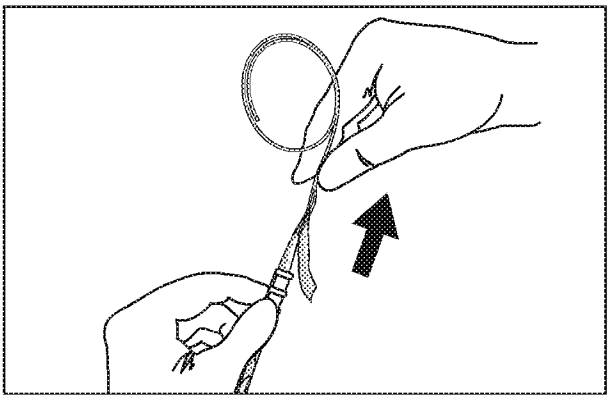


Figura 9C

IMPORTANTE: Não remova as cânulas GYNERCARE PROLIFT da doente até que o implante de rede esteja colocado de forma apropriada.

Caso se utilizem suturas, agrafos ou outros dispositivos de fixação em conjunto com a rede, recomenda-se que os mesmos sejam colocados a uma distância mínima de 6,5 mm do rebordo da rede.

ACTUAÇÃO

Estudos feitos em animais mostram que a implantação da rede GYNECARE GYNEMESH PS provoca uma reacção inflamatória mínima a ligeira, a qual é passageira e é seguida do depósito de uma fina camada fibrosa de tecido que pode crescer através dos intervalos da rede, incorporando assim a rede no tecido adjacente. A rede mantém-se macia e flexível, não se verificando dificuldades no processo de cicatrização normal da ferida. O material não é absorvido nem está sujeito a degradação ou enfraquecimento pela acção das enzimas dos tecidos.

CONTRA-INDICAÇÕES

Quando a rede GYNECARE GYNEMESH PS é utilizada em lactentes, crianças, mulheres grávidas ou que pretendam engravidar futuramente, o cirurgião deverá estar ciente de que este produto não tem elasticidade suficiente para acompanhar o crescimento da doente.

ADVERTÊNCIAS E PRECAUÇÕES

- Antes de utilizar os sistemas de reparação do pavimento pélvico GYNECARE PROLIFT, os utilizadores devem estar familiarizados com as técnicas e os procedimentos cirúrgicos que envolvem a reparação do pavimento pélvico e redes não absorvíveis.
- Devem ser seguidas práticas cirúrgicas aceitáveis na presença de feridas infectadas ou contaminadas.
- No pós-operatório, deverá ser recomendado à doente que se abstenha de ter relações sexuais, não levante pesos e/ou faça exercícios físicos (como ciclismo e correr) até que o médico determine ser adequado para a doente voltar às suas actividades normais.
- Deve evitar-se aplicar uma tensão excessiva no implante de rede durante o manuseamento.
- Deve consultar-se a técnica cirúrgica recomendada para o sistema de reparação do pavimento pélvico GYNECARE PROLIFT, para obter mais informações sobre os procedimentos GYNECARE PROLIFT.
- Os sistemas de reparação do pavimento pélvico GYNECARE PROLIFT deverão ser usados com precaução de forma a evitar lesões em vasos, nervos, bexiga e intestinos. O facto de ter atenção à anatomia da doente e à utilização adequada do dispositivo irá minimizar os riscos.
- Pode ocorrer dor transitória nas pernas, que geralmente pode ser controlada com analgésicos fracos.
- Não se deve manipular o dispositivo de recuperação GYNECARE PROLIFT com instrumentos afiados nem cortá-lo para alterar o seu comprimento.

REACÇÕES ADVERSAS

- As reacções adversas potenciais são aquelas tipicamente associadas a materiais cirurgicamente implantáveis, incluindo potenciação de infecção, inflamação, formação de aderências, formação de fístulas, erosão, extrusão e formação de tecido cicatricial originando contracção do implante.
- Podem ocorrer perfurações ou lacerações de vasos, nervos, bexiga, uretra ou intestino durante a passagem do guia GYNECARE PROLIFT, que podem exigir reparação cirúrgica.

ESTERILIZAÇÃO

Os sistemas de reparação do pavimento pélvico GYNECARE PROLIFT são esterilizados com óxido de etileno. NÃO REESTERILIZAR. NÃO REUTILIZAR. Não utilizar se a embalagem estiver aberta ou danificada. Descartar todos os dispositivos abertos, que tenham sido utilizados ou não.

ELIMINAÇÃO

Descartar os dispositivos e embalagens de acordo com a política e os procedimentos relativos a materiais e resíduos de risco biológico em vigor na sua instituição.

ARMAZENAMENTO

Condições recomendadas de armazenamento: temperatura ambiente controlada e humidade relativa (aproximadamente 25 °C, 60% de humidade relativa), afastado da humidade e calor directo. Não utilizar para além do prazo de validade.

Símbolos utilizados nas etiquetas

ESPAÑOL

Gynecare

PROLIFT*

Sistema de reparación del suelo pélvico total
Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior

Por favor lea con atención toda la información.
De no seguir las instrucciones correctamente, los dispositivos podrían no funcionar adecuadamente e incluso causar lesiones personales.

ATENCIÓN: las leyes federales de los EE.UU. restringen la venta de este dispositivo al personal facultativo o bajo su prescripción.

Se recomienda recibir la instrucción adecuada antes de utilizar los sistemas de reparación del suelo pélvico GYNECARE PROLIFT*. Coordine la instrucción con el representante de ventas de su compañía.

Refiérase a la técnica quirúrgica recomendada para los sistemas de reparación del suelo pélvico GYNECARE PROLIFT para obtener más información sobre los procedimientos GYNECARE PROLIFT.

INDICACIONES

Los sistemas de reparación del suelo pélvico total, anterior y posterior GYNECARE PROLIFT están indicados para el refuerzo del tejido y la estabilización prolongada de las estructuras fasciales del suelo pélvico en el prolapso de la pared vaginal donde debe realizarse el tratamiento quirúrgico, ya sea como soporte mecánico o como material de unión para el defecto fascial.

DESCRIPCIÓN

Los sistemas de reparación del suelo pélvico total, anterior y posterior GYNECARE PROLIFT constan de implantes de malla blanda PROLENE* no absorbibles GYNECARE GYNEMESH* PS previamente cortados y un juego de instrumental para facilitar la colocación de los implantes de malla. En la siguiente tabla se resumen los instrumentos incluidos en cada sistema:

SISTEMA DE REPARACIÓN	COMPONENTES			
	Implante de malla	Guía	Dispositivos de tracción	Cánulas
Total	1 total	1	6	6
Anterior	1 anterior	1	4	4
Posterior	1 posterior	1	2	2

Tabla 1 – Componentes del sistema de reparación del suelo pélvico GYNECARE PROLIFT

GYNECARE GYNEMESH PS

La malla GYNECARE GYNEMESH PS está fabricada con filamentos tejidos de polipropileno extruido de composición idéntica a la utilizada en la sutura de polipropileno PROLENE, suturas quirúrgicas no absorbibles, U.S.P. (ETHICON, INC.). Según se ha comprobado, este material no es reactivo cuando se emplea como sutura y retiene su resistencia indefinidamente en el uso clínico. La malla ofrece una resistencia, durabilidad y adaptabilidad quirúrgica excelentes, con suficiente porosidad para la necesaria integración del tejido. Contiene además monofilamentos de PROLENE de color azul que forman líneas de contraste con el resto de la malla. Ésta está fabricada con fibras monofilamento de diámetro reducido tejidas con un diseño único, que le otorga una flexibilidad casi un 50 por ciento superior a la de la malla PROLENE común. La malla está tejida mediante un proceso que entrelaza la unión de cada fibra y proporciona elasticidad en ambas direcciones. Esta construcción permite cortar la malla en cualquier forma o tamaño deseados sin que se desenrede. La elasticidad bidireccional le permite adaptarse a las diferentes tensiones presentes en el cuerpo.

Implante de malla total

El implante de malla total está fabricado con GYNECARE GYNEMESH PS y tiene la forma requerida para realizar una reparación vaginal total. El implante tiene 6 tiras: 4 para fijar la parte anterior del implante utilizando un transobturador y dos para fijar la parte posterior en el ligamento sacroespinoso de forma transglútea. Como alternativa, las 2 tiras posteriores pueden cortarse para reducir su longitud y fijarse en el ligamento sacroespinoso de forma vaginal. Las tiras anteriores proximales y distales tienen extremos cuadrados y triangulares, respectivamente, mientras que las tiras posteriores tienen extremos redondeados *(ver la figura 1)*.

Implante de malla anterior
El implante de malla anterior está fabricado con GYNECARE GYNEMESH PS y tiene la forma requerida para realizar la reparación de defectos vaginales anteriores. El implante tiene 4 tiras que se fijan con un transobturador. Las tiras anteriores proximales y distales tienen extremos cuadrados y triangulares, respectivamente *(ver la figura 1)*.

Implante de malla posterior
El implante de malla posterior está fabricado con GYNECARE GYNEMESH PS y tiene la forma requerida para reparar defectos en la cúpula vaginal posterior y/o apical. El implante tiene 2 tiras que se fijan en el ligamento sacroespinoso de forma transglútea. Como alternativa, las 2 tiras posteriores pueden cortarse para reducir su longitud y fijarse en el ligamento sacroespinoso de forma vaginal. Las tiras posteriores tienen extremos redondeados *(ver la figura 1)*.

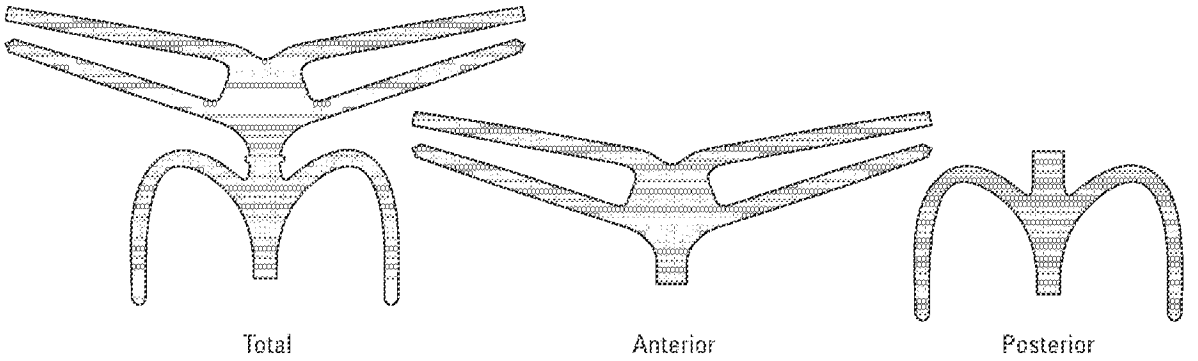


Figura 1 -- Implantes de malla (total, anterior y posterior)

Guía GYNECARE PROLIFT
La guía GYNECARE PROLIFT es un instrumento para uso en un solo paciente diseñado para crear vías de tejido que permitan colocar los implantes de malla total, anterior y posterior y para facilitar la colocación de la cánula GYNECARE PROLIFT. Su longitud y curvatura están específicamente diseñadas para crear vías de colocación adecuadas para todas las tiras de implante de malla. La guía GYNECARE PROLIFT es adecuada para ser utilizada a ambos lados de la paciente *(ver figura 2)*.

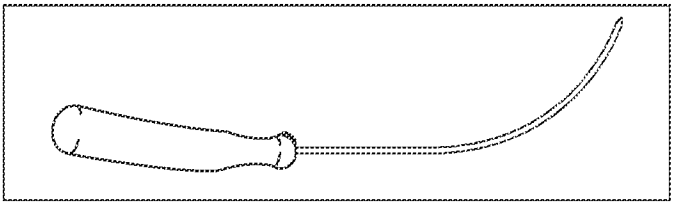


Figura 2 -- Guía GYNECARE PROLIFT

Cánula GYNECARE PROLIFT

La cánula GYNECARE PROLIFT es un instrumento para uso en un solo paciente que se utiliza junto con la guía GYNECARE PROLIFT para facilitar el pasaje de las tiras del implante y, al mismo tiempo, proteger el tejido adyacente. Cada cánula GYNECARE PROLIFT se coloca sobre la guía GYNECARE PROLIFT antes de pasarla y se deja en su lugar después de retirar la guía GYNECARE PROLIFT *(ver figura 3)*.

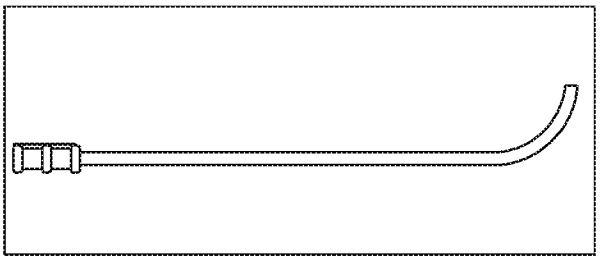


Figura 3 – Cánula GYNECARE PROLIFT

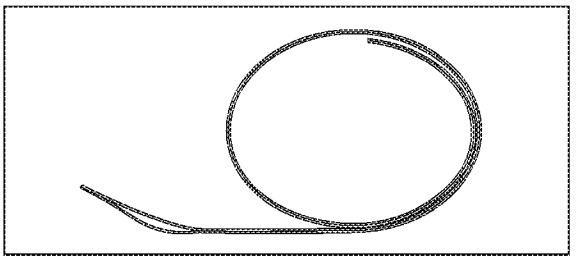


Figura 4 – Dispositivo de tracción GYNECARE PROLIFT

Dispositivo de tracción GYNECARE PROLIFT

El dispositivo de tracción GYNECARE PROLIFT es un instrumento para uso en un solo paciente diseñado para facilitar la colocación de las tiras de implante de malla. El dispositivo de tracción GYNECARE PROLIFT se pasa por la cánula GYNECARE PROLIFT previamente posicionada hasta que se recupera su extremo distal a través de la disección vaginal. El extremo distal del dispositivo de tracción GYNECARE PROLIFT tiene un lazo para capturar de forma segura la tira del implante de malla al retirarla a través de la cánula GYNECARE PROLIFT *(ver figura 4)*.

INSTRUCCIONES DE USO

NOTA: las siguientes figuras no ilustran técnicas clínicas sino que se limitan a mostrar el uso general de cada dispositivo.

Colocación de la cánula GYNECARE PROLIFT sobre la guía GYNECARE PROLIFT *(ver figuras 5A y 5B)*

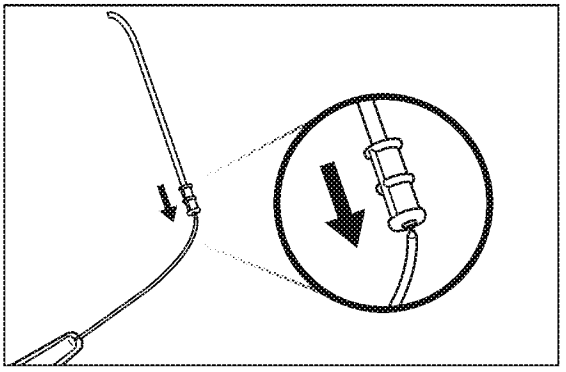


Figura 5A

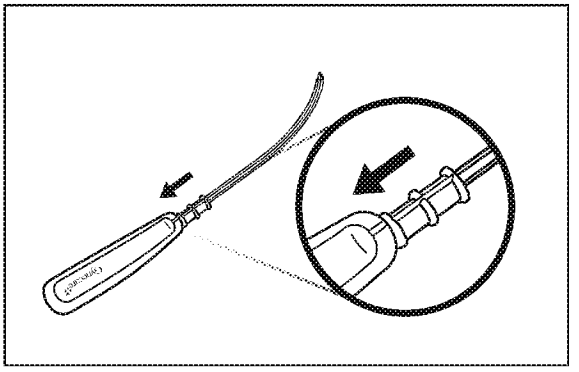


Figura 5B

IMPORTANTE: asegúrese de que la cánula GYNECARE PROLIFT y la guía GYNECARE PROLIFT están correctamente alineadas una vez montadas, según muestra la *figura 5B*.

Colocación de la cánula GYNECARE PROLIFT en la paciente ***(ver figuras 6A, 6B y 6C)***

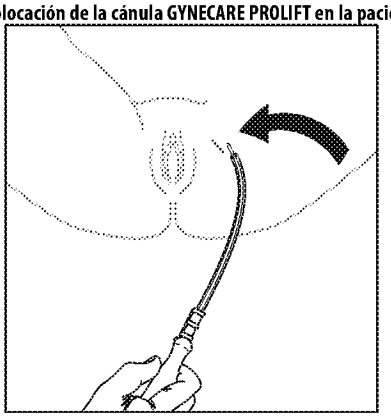


Figura 6A

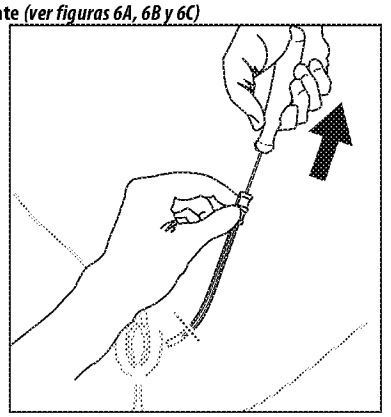


Figura 6B

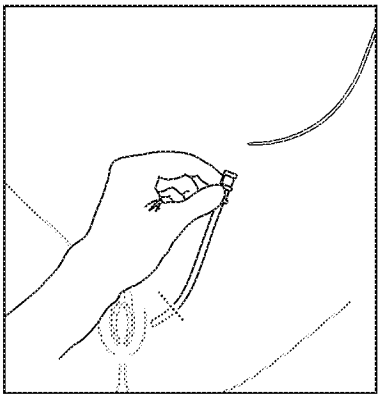


Figura 6C

Inserción y pasaje del dispositivo de tracción GYNECARE PROLIFT en la cánula GYNECARE PROLIFT ***(ver figuras 7A y 7B)***

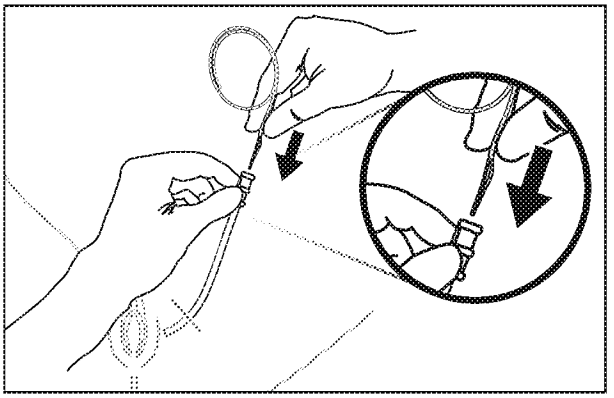


Figura 7A

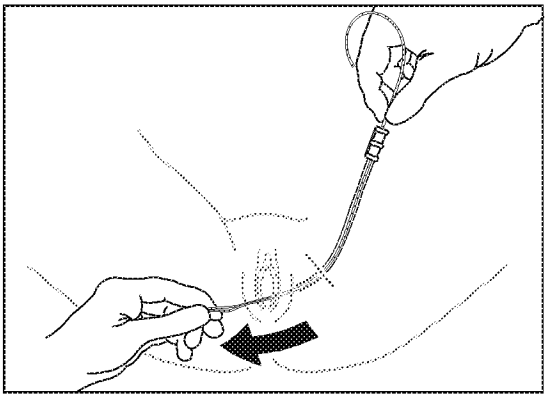


Figura 7B

IMPORTANTE: todas las cánulas GYNECARE PROLIFT y dispositivos de tracción GYNECARE PROLIFT suministrados deben colocarse antes de instalar los implantes de malla.

Captura de una tira de implante de malla con el dispositivo de tracción GYNECARE PROLIFT ***(ver figuras 8A, 8B y 8C)***

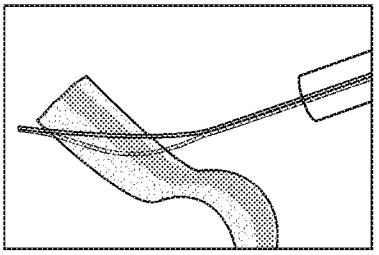


Figura 8A

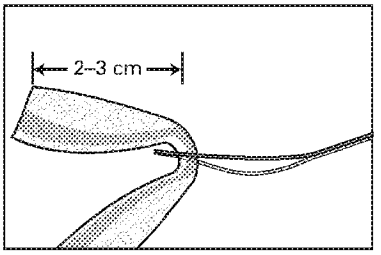


Figura 8B

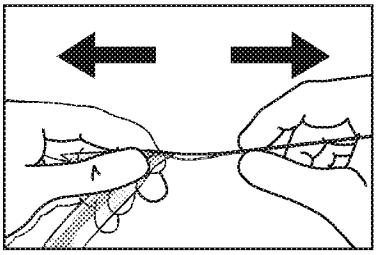


Figura 8C

Pasaje de una tira de implante de malla a través de la cánula GYNECARE PROLIFT ***(ver figuras 9A, 9B y 9C)***

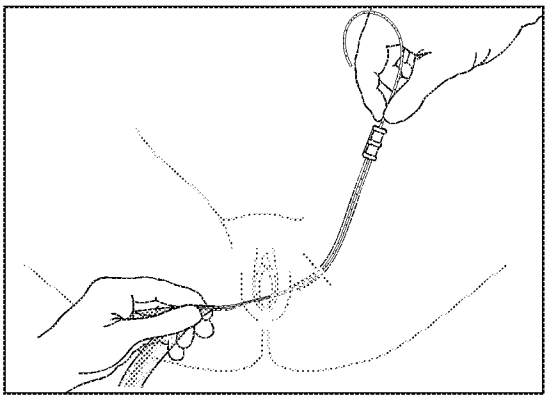


Figura 9A

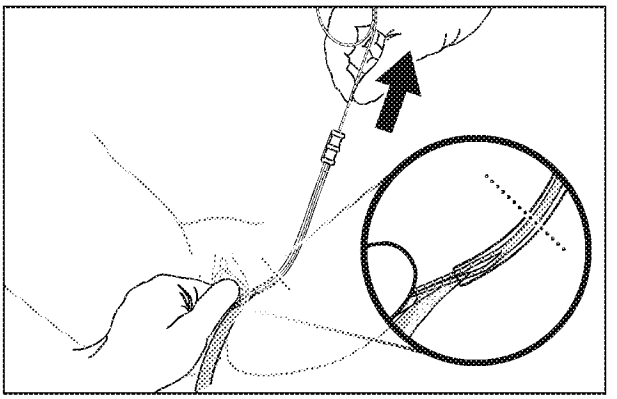


Figura 9B

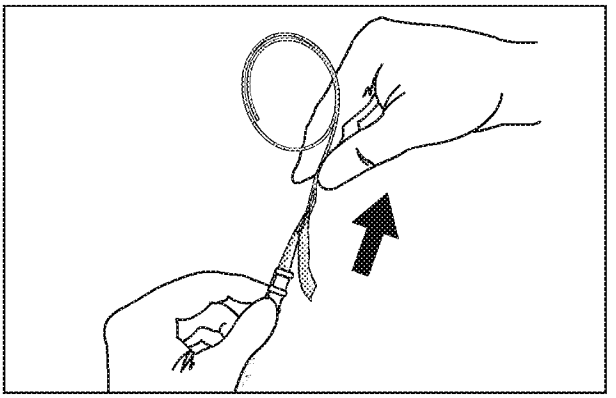


Figura 9C

IMPORTANTE: no retirar las cánulas GYNECARE PROLIFT de la paciente hasta haber posicionado correctamente el implante de malla.

En el caso de utilizar suturas, grapas u otros dispositivos de fijación junto con la malla, se recomienda colocarlos a al menos 6,5 mm del borde de la malla.

RENDIMIENTO

Los estudios realizados en animales demuestran que la implantación de la malla GYNECARE GYNEMESH PS provoca una reacción inflamatoria pasajera de mínima a leve, seguida por la deposición de una capa fibrosa delgada de tejido capaz de crecer entre los intersticios de la malla y, de esta manera, incorporarla al tejido adyacente. La malla se mantiene blanda y maleable y la cicatrización normal de la herida no se ve afectada de forma notoria. El material no es absorbido ni sometido a degradación o debilitamiento por la acción de las enzimas de los tejidos.

CONTRAINDICACIONES

Cuando la malla GYNECARE GYNEMESH PS se utiliza en bebés, niños, mujeres embarazadas o mujeres que tienen pensado tener hijos en el futuro, el cirujano debe ser consciente de que este producto no se estirará de forma significativa a medida que crece el paciente.

ADVERTENCIAS Y PRECAUCIONES

- Antes de utilizar los sistemas de reparación del suelo pélvico GYNECARE PROLIFT, se recomienda a los usuarios familiarizarse con los procedimientos y técnicas quirúrgicas para la reparación del suelo pélvico y mallas no absorbibles.
- Deben seguirse las prácticas quirúrgicas aceptables para el tratamiento de heridas infectadas o contaminadas.
- Debe recomendarse a la paciente que, después de la operación, se abstenga de tener relaciones sexuales, levantar objetos pesados y/o hacer ejercicio (por ejemplo, ir en bicicleta o correr) hasta que el médico determine que puede reanudar sus actividades normales.
- Evite colocar una tensión excesiva sobre el implante de malla durante su manipulación.
- Refiérase a la técnica quirúrgica recomendada para los sistemas de reparación del suelo pélvico GYNECARE PROLIFT para obtener más información sobre los procedimientos GYNECARE PROLIFT.
- Los sistemas de reparación del suelo pélvico GYNECARE PROLIFT deben utilizarse con cuidado para evitar dañar vasos grandes, nervios, la vejiga y los intestinos. Prestando atención a la anatomía de la paciente y utilizando el dispositivo correctamente se reducen los riesgos al mínimo.
- Puede producirse dolor temporal en la pierna pero, por lo general, puede tratarse con analgésicos suaves.
- No manipule el dispositivo de tracción GYNECARE PROLIFT con instrumentos afilados ni lo corte para modificar su longitud.

REACCIONES ADVERSAS

- Las posibles reacciones adversas son las típicamente asociadas con materiales implantables quirúrgicos e incluyen potenciamiento de infecciones, inflamación, formación de adherencias, formación de fístulas, erosión, extrusión y heridas que producen contracción del implante.
- Pueden producirse perforaciones o laceraciones en vasos, nervios, la vejiga, la uretra o los intestinos durante el pasaje de la guía GYNECARE PROLIFT que pueden necesitar reparación quirúrgica.

ESTERILIDAD

Los sistemas de reparación del suelo pélvico GYNECARE PROLIFT están esterilizados con óxido de etileno. NO REESTERILIZAR. NO REUTILIZAR. No utilizar si el envase está abierto o dañado. Desechar todos los dispositivos abiertos no utilizados.

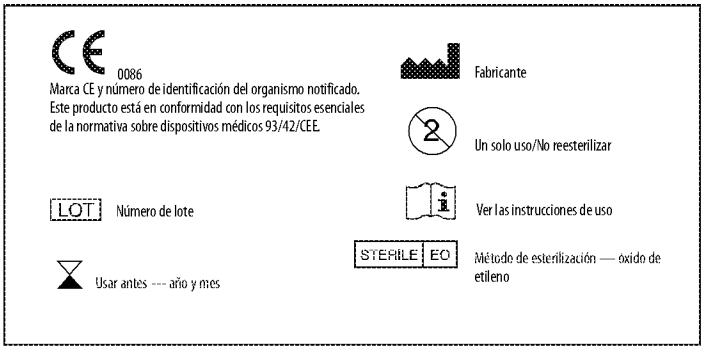
ELIMINACIÓN

Deseche los dispositivos y envases según las normas y procedimientos utilizados en su institución para materiales y desechos biopeligrosos.

ALMACENAJE

Condiciones de almacenamiento recomendadas: temperatura ambiente y humedad relativa controladas (aproximadamente 25 °C, 60 % humedad relativa), alejado de la humedad y el calor directo. No usarlo después de la fecha de caducidad.

Símbolos utilizados en las etiquetas



SVENSKA

Gynecare

PROLIFT*

System för total reparation av bäckenbotten
System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten

Läs noga igenom all information.

Underlåtenhet att noggrant följa dessa anvisningar kan resultera i att instrumenten inte fungerar korrekt och även medföra att skada uppstår.

OBS! Enligt amerikansk federal lagstiftning får denna anordning endast säljas av eller på order av läkare.

Utbildning i hur man använder GYNECARE PROLIFT* system för reparation av bäckenbotten rekommenderas och kan ordnas. Kontakta företagets försäljningsrepresentant för att planera utbildning.

Se rekommenderad kirurgisk teknik för GYNECARE PROLIFT system för reparation av bäckenbotten för ytterligare information om ingrepp med GYNECARE PROLIFT.

INDIKATIONER

GYNECARE PROLIFT system för total, främre och bakre reparation av bäckenbotten är indikerade för att stärka vävnad och för långvarig stabilisering av fasciala strukturer i bäckenbotten vid vaginalprolaps när kirurgisk behandling är planerad, antingen som mekaniskt stöd eller som brygga för att korrigera defekten i fascia.

BESKRIVNING

GYNECARE PROLIFT system för total, främre och bakre reparation av bäckenbotten består av tillklippta GYNECARE GYNEMESH* PS icke resorberbara PROLENE* mjuka nätimplantat och en uppsättning instrument för att underlätta implantatplacering. I följande tabell finns en sammanställning av de instrument som ingår i respektive system:

SYSTEM	KOMPONENTER			
	Nätimplantat	Guide	Grip-instrument	Kanyler
Total	1 total	1	6	6
Främre	1 främre	1	4	4
Bakre	1 bakre	1	2	2

Tabell 1 – GYNECARE PROLIFT komponenter i system för reparation av bäckenbotten

GYNECARE GYNEMESH PS

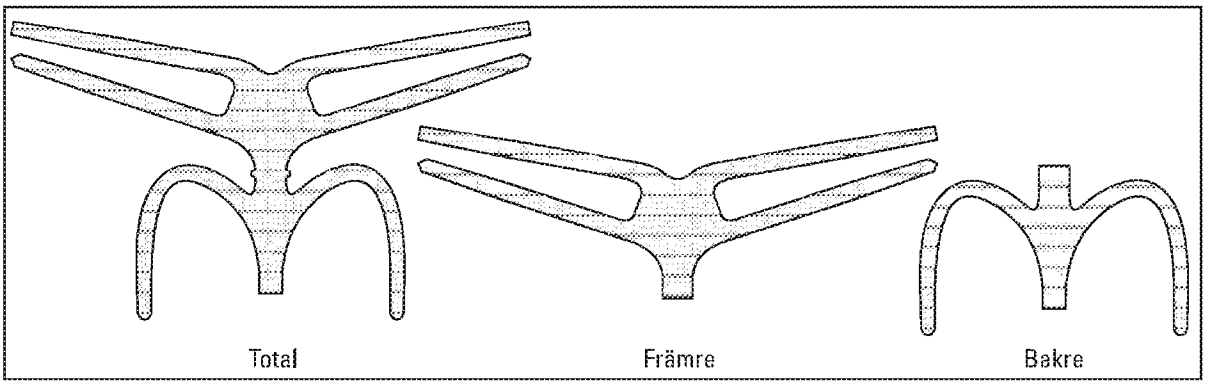
GYNECARE GYNEMESH PS är ett nät tillverkat av sammanvävda filament av strängsprutad polypropen med en sammansättning som är identisk med PROLENE icke resorberbar polypropensutur, U.S.P. (ETHICON, INC.). Detta material har vid användning som suturmaterial rapporterats vara icke-reaktivt och behålla sin styrka under obegränsad tid vid klinisk användning. Nätet är utomordentligt starkt, hållbart och kirurgiskt anpassningsbart och samtidigt tillräckligt poröst för att möjliggöra nödvändig vävnadsinväxt. Blå PROLENE monofilament har vävts in för att ge kontrasterande ränder i nätet. Nätet är gjort av monofilamentfiber med reducerad diameter, vävda i en unik design som ger ett nät som är ca 50 procent mer flexibelt än PROLENE-nät av standardtyp. Nätet är tillverkat enligt en process som länkar samman varje fiberkorsning vilket ger elasticitet i båda riktningarna. Tack vare denna konstruktion kan nätet klippas till i vilken form och storlek som helst utan att fransas upp. Denna tvåvägselasticitet gör att nätet kan anpassa sig till de varierande påfrestningar som uppstår i kroppen.

Total nätimplantat

Det totala nätimplantatet är tillverkat av GYNECARE GYNEMESH PS och utformat för total vaginal reparation. Implantatet har sex remsor: fyra för att fästa den främre delen av implantatet genom slyngingrepp och två för att fästa den bakre delen av implantatet i det sakrospinala ligamentet genom ett transglutealt ingrepp. Alternativt kan de två bakre remsorna klippas till och förkortas för att fästas i det sakrospinala ligamentet vid ingrepp genom vagina. De proximala och distala främre remsorna har raka respektive trekantiga ändar, medan de bakre remsorna har rundade ändar *(se figur 1)*.

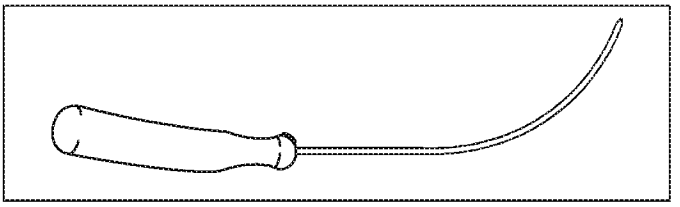
Främre nätimplantat
Det främre nätimplantatet är tillverkat av GYNECARE GYNEMESH PS och utformat för reparation av defekter i främre delen av vagina. Implantatet har fyra remsor som fästs genom ett slyngingrepp. De proximala och distala främre remsorna har raka respektive trekantiga ändar *(se figur 1)*.

Bakre nätimplantat
Det bakre nätimplantatet är tillverkat av GYNECARE GYNEMESH PS och utformat för reparation av defekter i bakre och/eller apikala delen av vagina. Implantatet har två remsor som fästs i det sakrospinala ligamentet genom ett transglutealt ingrepp. Alternativt kan de två bakre remsorna klippas till och förkortas för att fästas i det sakrospinala ligamentet vid ingrepp genom vagina. De bakre remsorna har rundade ändar *(se figur 1)*.



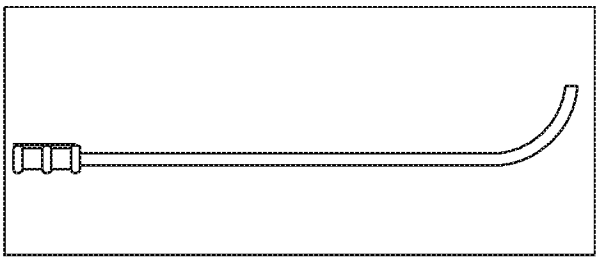
Figur 1 – Nätimplantat (total, främre och bakre)

GYNECARE PROLIFT guide
GYNECARE PROLIFT guide är engångsinstrument utformat för att skapa vägar i vävnaden för att placera nätimplantaten (total, främre och bakre) och för att underlätta placeringen av GYNECARE PROLIFT kanyl. Dess längd och böjning är speciellt utformad för att skapa korrekta vägar för placering av alla nätimplantatremsor. GYNECARE PROLIFT är lämplig att använda på patientens båda sidor *(se figur 2)*.

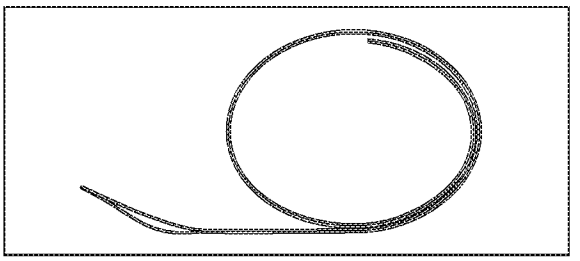


Figur 2 – GYNECARE PROLIFT guide

GYNECARE PROLIFT kanyl
GYNECARE PROLIFT kanyl är ett engångsinstrument som används tillsammans med GYNECARE PROLIFT guide för att underlätta passage av implantatremsorna samtidigt som omgivande vävnad skyddas. GYNECARE PROLIFT kanyl placeras över GYNECARE PROLIFT guide före passage och ska sitta kvar när GYNECARE PROLIFT guide dras tillbaka *(se figur 3)*.



Figur 3 – GYNECARE PROLIFT kanyl



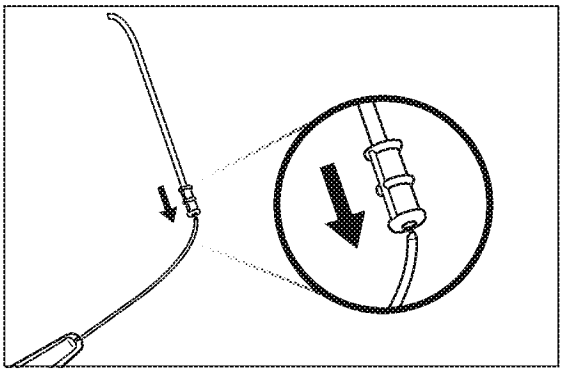
Figur 4 – GYNECARE PROLIFT gripinstrument

GYNECARE PROLIFT gripinstrument
GYNECARE PROLIFT gripinstrument är ett engångsinstrument avsett att underlätta placeringen av nätimplantatremsorna. GYNECARE PROLIFT gripinstrument dras genom den tidigare placerade GYNECARE PROLIFT kanylen tills dess distala ände går igenom den vaginala dissektionen. Den distala änden av GYNECARE PROLIFT gripinstrument har en ögla för att på ett säkert sätt gripa tag i nätimplantatremsan när den dras ut genom GYNECARE PROLIFT kanyl *(se figur 4)*.

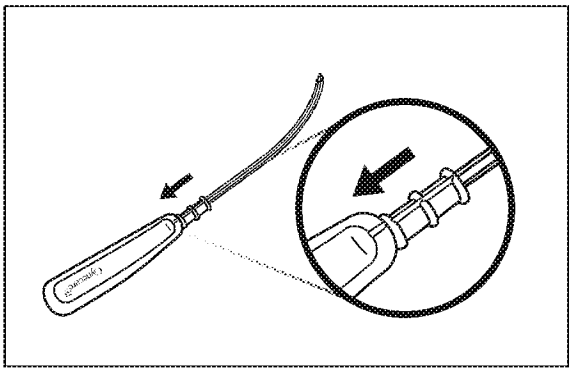
BRUKSANVISNING

ANM: Bilderna nedan är inte avsedda att tillhandahålla någon klinisk utbildning och visar endast allmän användning av respektive instrument.

Placering av GYNECARE PROLIFT kanyl i GYNECARE PROLIFT guide *(se figur 5A och 5B)*



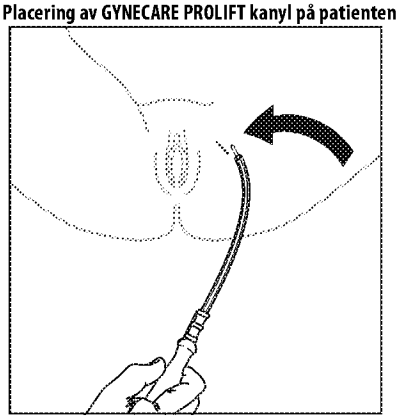
Figur 5A



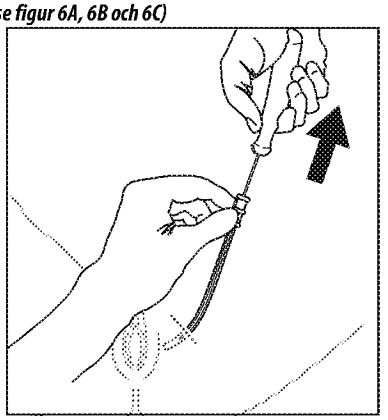
Figur 5B

VIKTIGT: Kontrollera att GYNECARE PROLIFT kanyl och GYNECARE PROLIFT guide placeras korrekt vid hopsättning, *se figur 5B*.

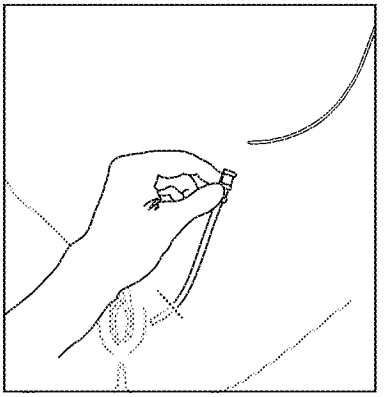
Placering av GYNECARE PROLIFT kanyl på patienten ***(se figur 6A, 6B och 6C)***



Figur 6A

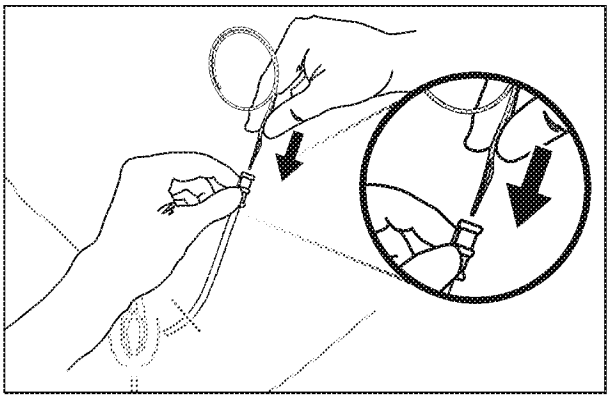


Figur 6B

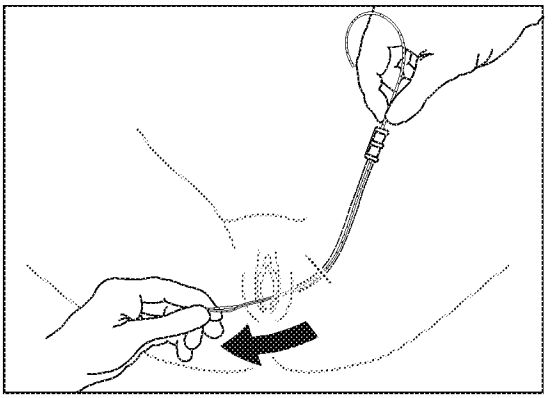


Figur 6C

Införande och passage av GYNECARE PROLIFT gripinstrument i GYNECARE PROLIFT kanyl ***(se figur 7A och 7B)***



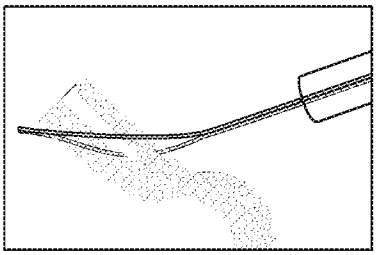
Figur 7A



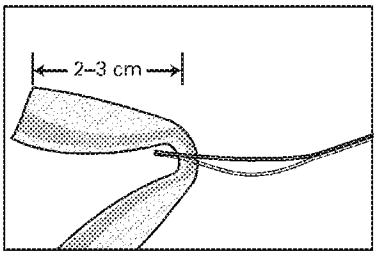
Figur 7B

VIKTIGT: Alla medföljande GYNECARE PROLIFT kanyler och GYNECARE PROLIFT gripinstrument ska vara på plats innan nätimplantatet fästs.

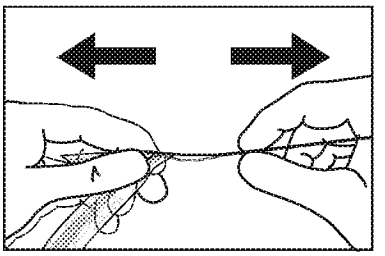
Grip tag i en nätimplantatremsa med GYNECARE PROLIFT gripinstrument ***(se figur 8A, 8B och 8C)***



Figur 8A

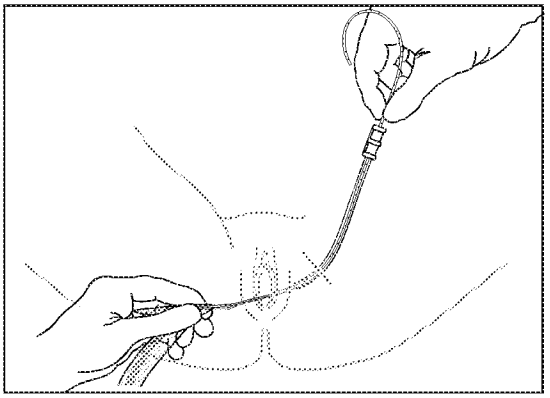


Figur 8B

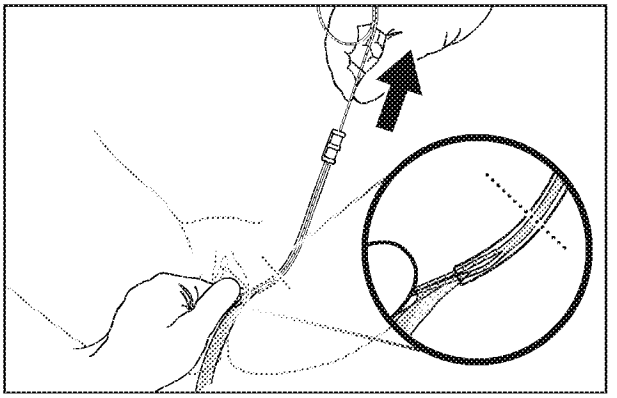


Figur 8C

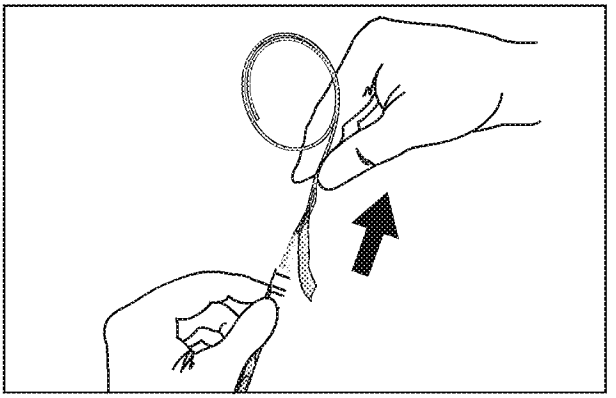
Passage av nätimplantatremsa genom GYNECARE PROLIFT kanyl *(se figur 9A, 9B och 9C)*



Figur 9A



Figur 9B



Figur 9C

VIKTIGT: Ta inte bort inte GYNECARE PROLIFT kanyler från patienten förrän nätimplantatet är korrekt placerat.

Om suturer, klamrar eller andra fixationsinstrument används tillsammans med nätet bör dessa placeras minst 6,5 mm från nätets kant.

PRESTANDA

Djurstudier visar att implantation av GYNECARE GYNEMESH PH nät framkallar en minimal till lindrig inflammatorisk reaktion, vilken är övergående och efterföljs av deponering av ett tunt bindvävslager som kan växa igenom nätmaskorna så att nätet införlivas med intilliggande vävnad. Nätet förblir mjukt och formbart och den normala sårläkningen påverkas inte märkbart. Materialet resorberas inte och bryts inte heller ned eller försvagas av vävnadsenzymer.

KONTRAINDIKATIONER

Vid användning av GYNECARE GYNEMESH PS nät på spädbarn, barn, gravida eller kvinnor som planerar framtida graviditet skall kirurgen vara medveten om att denna produkt inte kan sträckas i någon signifikant omfattning efterhand som patienten växer.

VARNINGAR OCH FÖRSIKTIGHETSÅTGÄRDER

- Användare ska ha erfarenhet av operationsteknik som används vid reparation av bäckenbotten samt icke resorberbara nät innan de börjar använda GYNECARE PROLIFT system för reparation av bäckenbotten.
- Accepterad kirurgisk praxis skall följas om det finns infekterade eller kontaminerade sår.
- Efter operationen bör patienten rådas att avstå från samlag, tunga lyft och/eller motion (t.ex. cykla, jogga) tills läkaren meddelar att det är lämpligt för patienten att återgå till sina normala aktiviteter.
- Undvik att belasta nätimplantatet kraftigt vid behandlingen.
- Se rekommenderad kirurgisk teknik för GYNECARE PROLIFT system för reparation av bäckenbotten för ytterligare information om ingrepp med GYNECARE PROLIFT.
- GYNECARE PROLIFT system för reparation av bäckenbotten ska användas med försiktighet för att undvika skador på blodkärl, nerver, urinblåsa och tarmar. Hänsynstagande till patientens anatomi och korrekt användning av instrumentet bidrar till att minimera riskerna.
- Övergående bensmärtor kan förekomma och kan vanligen behandlas med lätta analgetika.
- Manipulera inte GYNECARE PROLIFT gripinstrument med vassa instrument och klipp inte i det för att ändra längden.

BIVERKNINGAR

- Möjliga biverkningar är sådana som vanligen kan sättas i samband med kirurgiska implantat, däribland försämring av infektion, inflammation, adherensbildning, fistelbildning, erosion, extrusion och ärrbildning som kan leda till kontraktion av implantatet.
- Punktion eller laceration av blodkärl, nerver, urinblåsa, urinrör eller tarmar kan förekomma i samband med passage av GYNECARE PROLIFT guide och kan kräva kirurgisk reparation.

STERILITET

GYNECARE PROLIFT system för reparation av bäckenbotten är steriliserade med etylenoxid. FÅR EJ RESTERILISERAS. FÅR EJ ÅTERANVÄNDAS. Produkterna får ej användas om förpackningen varit öppnad tidigare eller är skadad. Kassera oanvända produkter vars förpackningar har öppnats.

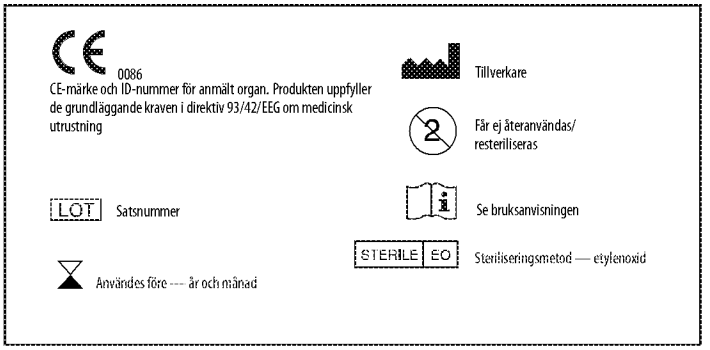
KASSERING

Kassera instrument och förpackningar enligt de regler och rutiner som gäller på din arbetsplats för hantering av biologiskt riskavfall.

FÖRVARING

Rekommenderade förvaringsförhållanden: kontrollerad rumstemperatur och relativ luftfuktighet (cirka 25 °C, 60 % relativ luftfuktighet). Skyddas mot fukt och direkt värme. Får ej användas efter utgångsdatum.

Symboler på etiketterna



ΕΛΛΗΝΙΚΑ

Gynecare

PROLIFT*

Σύστημα ολικής αποκατάστασης πυελικού εδάφους
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους

Διαβάστε προσεκτικά όλες τις πληροφορίες.

Εάν δεν ακολουθήσετε σωστά τις οδηγίες, οι συσκευές πιθανόν να μη λειτουργήσουν σωστά και ενδέχεται να προκληθεί τραυματισμός.

ΠΡΟΣΟΧΗ: Η ομοσπονδιακή νομοθεσία (των Η.Π.Α.) περιορίζει την πώληση της συσκευής αυτής σε ιατρούς ή κατόπιν εντολής ιατρού.

Συνιστάται και διατίθεται εκπαίδευση στη χρήση των συστημάτων αποκατάστασης πυελικού εδάφους GYNECARE PROLIFT*. Επικοινωνήστε με τον αντιπρόσωπο πωλήσεων της εταιρείας για να κανονίσετε την εκπαίδευση.

Ανατρέξτε στη συνιστώμενη χειρουργική τεχνική για τα συστήματα αποκατάστασης πυελικού εδάφους GYNECARE PROLIFT για επιπλέον πληροφορίες σχετικά με τις διαδικασίες GYNECARE PROLIFT.

ΕΝΔΕΙΞΕΙΣ

Τα συστήματα ολικής αποκατάστασης, αποκατάστασης πρόσθιου και οπίσθιου πυελικού τοιχώματος GYNECARE PROLIFT ενδείκνυνται για την ενίσχυση ιστού και τη μακροχρόνια σταθεροποίηση των περιτοναϊκών δομών του πυελικού εδάφους, σε περιπτώσεις πρόπτωσης του κολπικού τοιχώματος όπου επίκειται χειρουργική αντιμετώπιση, είτε ως μηχανική υποστήριξη είτε ως υλικό γεφύρωσης του ελλείμματος της περιτονίας.

ΠΕΡΙΓΡΑΦΗ

Το σύστημα ολικής αποκατάστασης και τα συστήματα αποκατάστασης του πρόσθιου και του οπίσθιου πυελικού τοιχώματος GYNECARE PROLIFT αποτελούνται από ήδη κομμένα εμφυτεύματα μαλακού πλέγματος GYNECARE GYNEMESH* PS από μη απορροφήσιμο υλικό PROLENE* και από ένα σετ εργαλείων για τη διευκόλυνση της τοποθέτησης των εμφυτευμάτων πλέγματος. Ο παρακάτω πίνακας δίνει συνοπτικά τα εργαλεία που περιλαμβάνονται με κάθε σύστημα:

ΣΥΣΤΗΜΑ ΕΠΙΣΚΕΥΗΣ	ΕΞΑΡΤΗΜΑΤΑ			
	Εμφύτευμα πλέγματος	Οδηγός	Συσκευές ανάκτησης	Σωληνίσκοι
Ολικό	1 ολικό	1	6	6
Πρόσθιο	1 πρόσθιο	1	4	4
Οπίσθιο	1 οπίσθιο	1	2	2

Πίνακας 1 - Εξαρτήματα συστημάτων αποκατάστασης πυελικού εδάφους GYNECARE PROLIFT

GYNECARE GYNEMESH PS

Το πλέγμα GYNECARE GYNEMESH PS κατασκευάζεται από πλεκτά νήματα εξωθημένου πολυπροπυλενίου, πανομοιότυπα σε σύνθεση με εκείνα που χρησιμοποιούνται στο ράμμα πολυπροπυλενίου, στα μη απορροφήσιμα χειρουργικά ράμματα PROLENE, κατά U.S.P. (ETHICON, INC.). Το υλικό αυτό, όταν χρησιμοποιείται ως ράμμα, έχει αναφερθεί ότι είναι μη δραστικό και ότι διατηρεί την αντοχή του επ' αόριστο κατά την κλινική χρήση. Το πλέγμα χαρακτηρίζεται από εξαιρετική αντοχή, διάρκεια ζωής και δυνατότητα προσαρμογής σε διάφορες χειρουργικές τεχνικές, καθώς διαθέτει επαρκώς πορώδη δομή που επιτρέπει την απαραίτητη διείσδυση ιστών. Για την εμφάνιση λωρίδων αντίθεσης στο πλέγμα, έχουν ενσωματωθεί μεμονωμένα μπλε νήματα PROLENE. Το πλέγμα κατασκευάζεται από μονόκλωνες ίνες μειωμένης διαμέτρου, πλεγμένες ώστε να σχηματίζουν ένα μοναδικό σχέδιο που καταλήγει σε πλέγμα, το οποίο είναι περίπου 50 τοις εκατό πιο εύκαμπτο από το τυπικό πλέγμα PROLENE. Το πλέγμα πλέκεται με μια διαδικασία που συνδέει μεταξύ τους τις ενώσεις των ινών, εξασφαλίζοντας έτσι την ελαστικότητα και προς τις δύο διευθύνσεις. Η κατασκευή αυτή επιτρέπει την κοπή του πλέγματος σε οποιοδήποτε επιθυμητό σχήμα ή μέγεθος, χωρίς να ξετυλίγεται. Η ελαστικότητα προς δύο κατευθύνσεις επιτρέπει την προσαρμογή του στις διάφορες τάσεις που παρουσιάζονται στο σώμα.

Ολικό εμφύτευμα πλέγματος

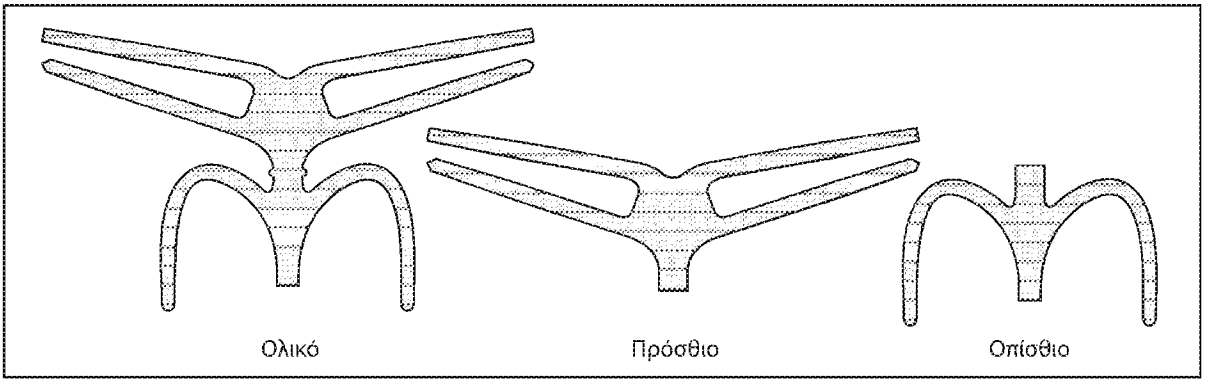
Το ολικό εμφύτευμα πλέγματος κατασκευάζεται από GYNECARE GYNEMESH PS και έχει σχήμα κατάλληλο για την εκτέλεση ολικής κολπικής αποκατάστασης. Το εμφύτευμα διαθέτει 6 ιμάντες: οι 4 προορίζονται για την καθήλωση του πρόσθιου τμήματος του εμφυτεύματος μέσω διαθυροειδούς προσέγγισης και οι δύο για την καθήλωση του οπίσθιου τμήματος του εμφυτεύματος στον ιερονωτιαίο σύνδεσμο, μέσω διαγλουτιαίας προσέγγισης. Εναλλακτικά, οι 2 οπίσθιοι ιμάντες μπορούν να κοπούν στο κατάλληλο μήκος και να στερεωθούν στον ιερονωτιαίο σύνδεσμο μέσω κολπικής προσέγγισης. Οι εγγύς και περιφερικοί πρόσθιοι ιμάντες φέρουν τετράγωνα και τριγωνικά άκρα, αντίστοιχα, ενώ οι οπίσθιοι ιμάντες φέρουν στρογγυλεμένα άκρα *(βλ. εικόνα 1)*.

Πρόσθιο εμφύτευμα πλέγματος

Το πρόσθιο εμφύτευμα πλέγματος κατασκευάζεται από GYNECARE GYNEMESH PS και έχει σχήμα κατάλληλο για την αποκατάσταση πρόσθιων κολπικών βλαβών. Το εμφύτευμα φέρει 4 ιμάντες, οι οποίοι στερεώνονται μέσω διαθυροειδούς προσέγγισης. Οι εγγύς και περιφερικοί πρόσθιοι ιμάντες φέρουν τετράγωνα και τριγωνικά άκρα, αντίστοιχα *(βλ. εικόνα 1)*.

Οπίσθιο εμφύτευμα πλέγματος

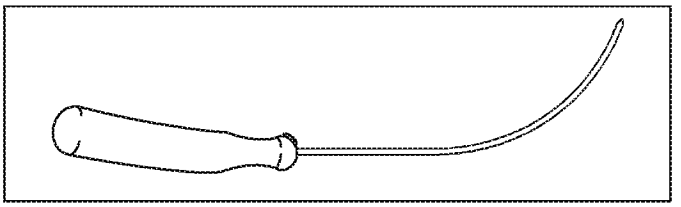
Το οπίσθιο εμφύτευμα πλέγματος κατασκευάζεται από GYNECARE GYNEMESH PS και έχει σχήμα κατάλληλο για την αποκατάσταση οπίσθιων και/ή κορυφαίων κολπικών βλαβών. Το εμφύτευμα φέρει 2 ιμάντες, οι οποίοι στερεώνονται στον ιερονωτιαίο σύνδεσμο μέσω διαγλουτιαίας προσέγγισης. Εναλλακτικά, οι 2 οπίσθιοι ιμάντες μπορούν να κοπούν στο κατάλληλο μήκος και να στερεωθούν στον ιερονωτιαίο σύνδεσμο μέσω κολπικής προσέγγισης. Οι οπίσθιοι ιμάντες φέρουν στρογγυλεμένα άκρα *(βλ. εικόνα 1)*.



Εικόνα 1 - Εμφυτεύματα πλέγματος (ολικό, πρόσθιο και οπίσθιο)

Οδηγός GYNECARE PROLIFT

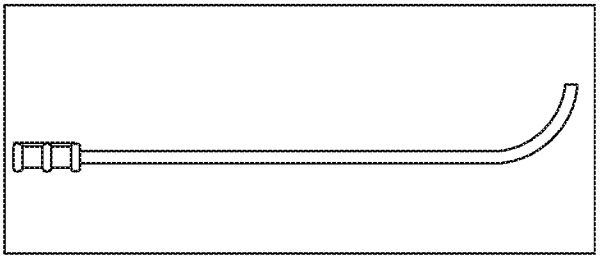
Ο οδηγός GYNECARE PROLIFT είναι ένα εργαλείο για χρήση σε μία μόνον ασθενή, σχεδιασμένο ώστε να δημιουργεί οδούς στον ιστό για τη διευκόλυνση της τοποθέτησης των ολικών, των πρόσθιων και των οπίσθιων εμφυτευμάτων πλέγματος, καθώς και για τη διευκόλυνση της τοποθέτησης του σωληνίσκου GYNECARE PROLIFT. Το μήκος και η καμπυλότητά τους είναι ειδικά σχεδιασμένα για να δημιουργούν τις κατάλληλες οδούς τοποθέτησης για όλους τους ιμάντες των εμφυτευμάτων πλέγματος. Ο οδηγός GYNECARE PROLIFT είναι κατάλληλος για χρήση και στις δύο πλευρές της ασθενούς *(βλ. εικόνα 2)*.



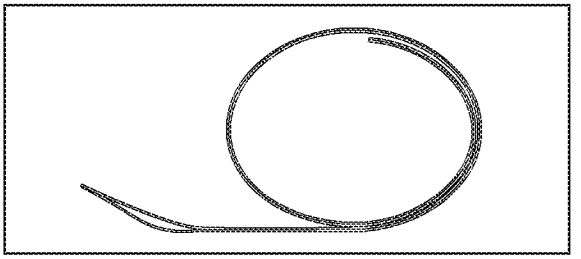
Εικόνα 2 - Οδηγός GYNECARE P IFT

Σωληνάριο GYNECARE PROLIFT

Ο σωληνίσκος GYNECARE PROLIFT είναι ένα εργαλείο για χρήση σε μία μόνον ασθενή, το οποίο χρησιμοποιείται σε συνδυασμό με τον οδηγό GYNECARE PROLIFT, για τη διευκόλυνση της διέλευσης των ιμάντων των εμφυτευμάτων, προστατεύοντας ταυτόχρονα τους περιβάλλοντες ιστούς. Κάθε σωληνίσκος GYNECARE PROLIFT τοποθετείται επάνω από τον οδηγό GYNECARE PROLIFT πριν από τη διέλευση και παραμένει στη θέση αυτή μετά την απομάκρυνση του οδηγού GYNECARE PROLIFT *(βλ. εικόνα 3)*.



Εικόνα 3 - Σω ECARE PROLIFT



Εικόνα 4 - Συσκευή ανάκτησης GYNECARE PROLIFT

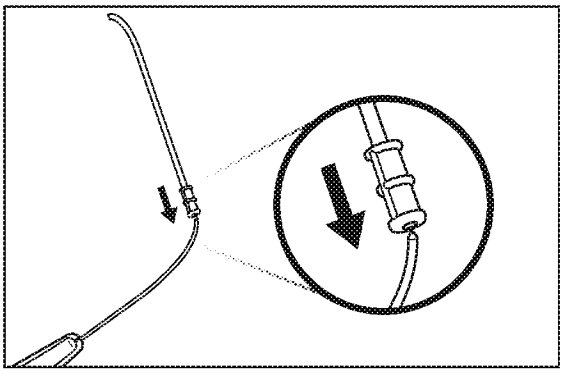
Συσκευή ανάκτησης GYNECARE PROLIFT

Η συσκευή ανάκτησης GYNECARE PROLIFT είναι ένα εργαλείο για χρήση σε μία μόνον ασθενή, το οποίο έχει σχεδιαστεί για να διευκολύνει την τοποθέτηση των ιμάντων των εμφυτευμάτων πλέγματος. Η συσκευή ανάκτησης GYNECARE PROLIFT διέρχεται διαμέσου του σωληνίσκου GYNECARE PROLIFT που έχει τοποθετηθεί προηγουμένως, μέχρις ότου το περιφερικό άκρο του ανακτηθεί διαμέσου της κολπικής διατομής. Το περιφερικά άκρο της συσκευής ανάκτησης GYNECARE PROLIFT φέρει ένα βρόχο για την ασφαλή σύλληψη του ιμάντα του εμφυτεύματος πλέγματος, καθώς ο ιμάντας έλκεται προς τα έξω διαμέσου του σωληνίσκου GYNECARE PROLIFT *(βλ. εικόνα 4)*.

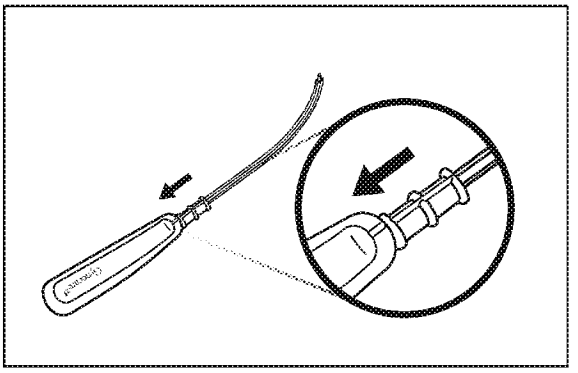
ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

ΣΗΜΕΙΩΣΗ: Καμία από τις παρακάτω εικόνες δεν προορίζεται να παρέχει κλινική εκπαίδευση, αλλά παρουσιάζουν απλώς τη γενική χρήση κάθε συσκευής.

Τοποθέτηση του σωληνίσκου GYNECARE PROLIFT μέσα στον οδηγό GYNECARE PROLIFT *(βλ. εικόνες 5A και 5B)*



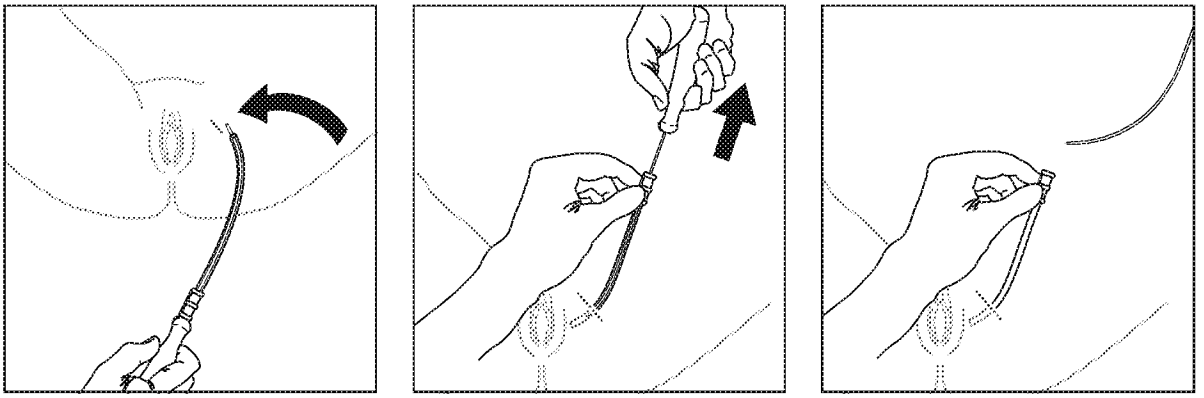
Εικόνα 5A



Εικόνα 5B

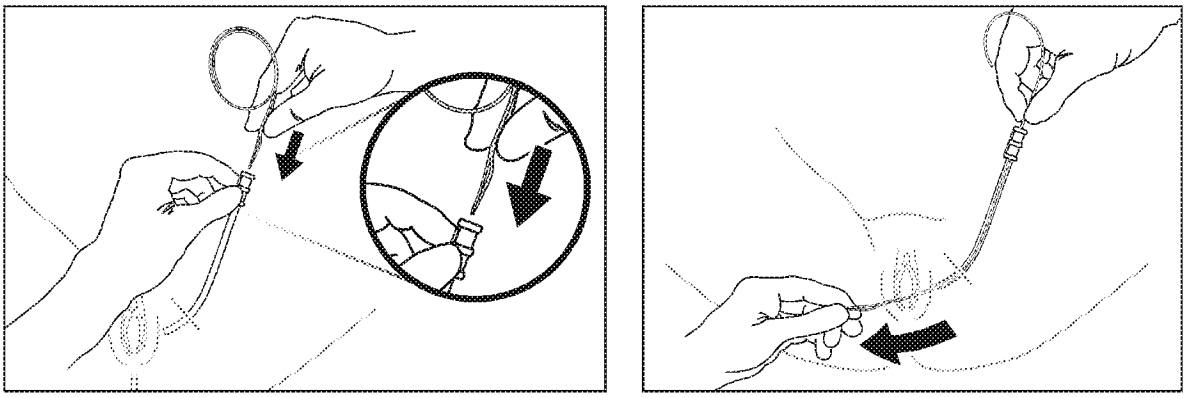
ΣΗΜΑΝΤΙΚΟ: Βεβαιωθείτε ότι ο σωληνίσκος GYNECARE PROLIFT και ο οδηγός GYNECARE PROLIFT είναι σωστά ευθυγραμμισμένοι κατά τη συναρμολόγηση, όπως παρουσιάζεται στην *εικόνα 5B*.

Τοποθέτηση του σωληνίσκου GYNECARE PROLIFT στην ασθενή *(βλ. εικόνες 6Α, 6Β και 6Γ)*



Εικόνα 6Α *Εικόνα 6Β* *Εικόνα 6Γ*

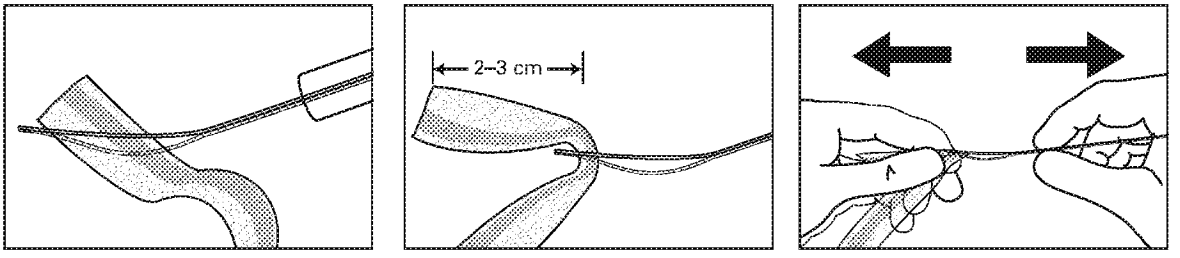
Εισαγωγή και διέλευση της συσκευής ανάκτησης GYNECARE PROLIFT μέσα στο σωληνίσκο GYNECARE PROLIFT *(βλ. εικόνες 7Α και 7Β)*



Εικόνα 7Α *Εικόνα 7Β*

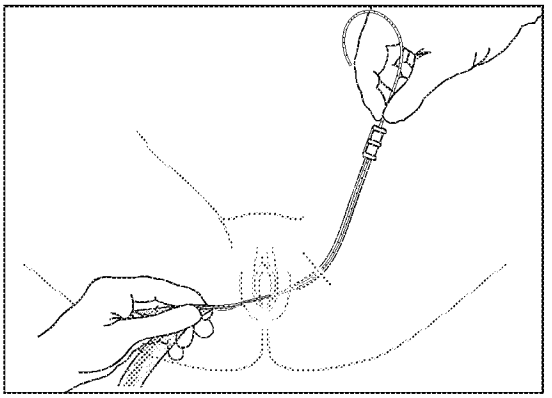
ΣΗΜΑΝΤΙΚΟ: Όλοι οι σωληνίσκοι GYNECARE PROLIFT και οι συσκευές ανάκτησης GYNECARE PROLIFT που παρέχονται πρέπει να τοποθετηθούν πριν από την εγκατάσταση του εμφυτεύματος πλέγματος.

Σύλληψη ενός ιμάντα εμφυτεύματος πλέγματος με τη συσκευή ανάκτησης GYNECARE PROLIFT *(βλ. εικόνες 8Α, 8Β και 8Γ)*

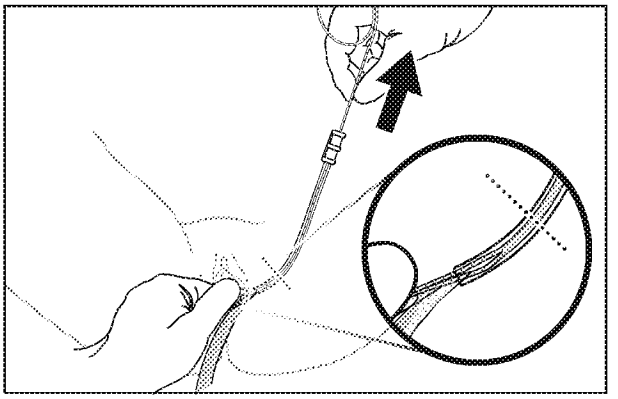


Εικόνα 8Α *Εικόνα 8Β* *Εικόνα 8Γ*

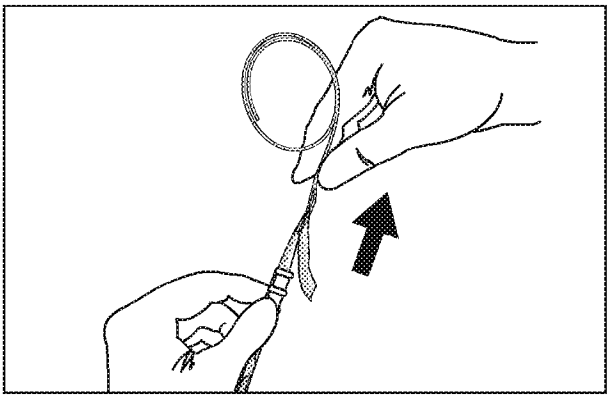
Διέλευση ενός ιμάντα εμφυτεύματος πλέγματος διαμέσου του σωληνίσκου GYNECARE PROLIFT *(βλ. εικόνες 9Α, 9Β και 9Γ)*



Εικόνα 9Α



Εικόνα 9Β



Εικόνα 9Γ

ΣΗΜΑΝΤΙΚΟ: Οι σωληνίσκοι GYNECARE PROLIFT θα πρέπει να αφαιρούνται από την ασθενή μόνον όταν το εμφύτευμα πλέγματος έχει τοποθετηθεί σωστά.

Σε περίπτωση που, σε συνδυασμό με το πλέγμα, χρησιμοποιηθούν ράμματα, συνδετήρες ή άλλες διατάξεις καθήλωσης, συνιστάται αυτές να τοποθετηθούν τουλάχιστον 6,5 mm από την παρυφή του πλέγματος.

ΑΠΟΔΟΣΗ

Μελέτες σε ζώα δείχνουν ότι η εμφύτευση πλέγματος GYNECARE GYNEMESH PS προκαλεί μια ελάχιστη έως πολύ μικρή φλεγμονώδη αντίδραση που είναι παροδική και ακολουθείται από την εναπόθεση ενός λεπτού ινώδους στρώματος ιστού, το οποίο μπορεί να αναπτυχθεί διαμέσου των διάκενων του πλέγματος, ενσωματώνοντας έτσι το πλέγμα στον παρακείμενο ιστό. Το πλέγμα παραμένει μαλακό και εύπλαστο, ενώ η φυσιολογική επούλωση του τραύματος δεν επηρεάζεται εμφανώς. Το υλικό δεν απορροφάται, ούτε υφίσταται αποδόμηση ή εξασθένηση από τη δράση των ενζύμων του ιστού.

ΑΝΤΕΝΔΕΙΞΕΙΣ

Όταν το πλέγμα GYNECARE GYNEMESH PS χρησιμοποιείται σε βρέφη, σε παιδιά, σε εγκύους ή σε γυναίκες που σκοπεύουν να τεκνοποιήσουν στο μέλλον, ο χειρουργός θα πρέπει να γνωρίζει ότι αυτό το προϊόν δεν θα εκταθεί σε σημαντικό βαθμό καθώς η ασθενής αναπτύσσεται.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ

- Πριν από τη χρήση των συστημάτων αποκατάστασης πυελικού εδάφους GYNECARE PROLIFT, οι ιατροί που το χρησιμοποιούν θα πρέπει να είναι εξοικειωμένοι με τις χειρουργικές διαδικασίες και τεχνικές που σχετίζονται με την αποκατάσταση πυελικού εδάφους και τη χρήση μη απορροφήσιμων πλεγμάτων.
- Σε περιπτώσεις τραυμάτων που έχουν υποστεί λοίμωξη ή μόλυνση, θα πρέπει να ακολουθούνται οι γενικά αποδεκτές χειρουργικές πρακτικές.
- Μετά από την επέμβαση, συνιστάται στην ασθενή να μην έλθει σε σεξουαλική επαφή, να αποφεύγει να σηκώνει βάρη και/ή να ασκείται (π.χ. ποδηλασία, τρέξιμο), μέχρις ότου ο ιατρός της καθορίσει ότι μπορεί να επανέλθει στις κανονικές της δραστηριότητες.
- Αποφύγετε την εφαρμογή υπερβολικής τάσης στο εμφύτευμα πλέγματος κατά το χειρισμό του.
- Ανατρέξτε στη συνιστώμενη χειρουργική τεχνική για το σύστημα αποκατάστασης πυελικού εδάφους GYNECARE PROLIFT για επιπλέον πληροφορίες σχετικά τις διαδικασίες GYNECARE PROLIFT.
- Τα συστήματα αποκατάστασης πυελικού εδάφους GYNECARE PROLIFT πρέπει να χρησιμοποιούνται με προσοχή ώστε να αποφευχθούν τυχόν βλάβες σε αγγεία, σε νεύρα, στην ουροδόχο κύστη και το έντερο. Οι κίνδυνοι ελαχιστοποιούνται εάν δοθεί προσοχή στην ανατομία της ασθενούς και στη σωστή χρήση της συσκευής.
- Ενδέχεται να εμφανιστεί παροδικό άλγος στα πόδια, το οποίο συνήθως μπορεί να αντιμετωπιστεί με ήπια αναλγητικά.
- Μη χειρίζεστε τη συσκευή ανάκτησης GYNECARE PROLIFT με αιχμηρά εργαλεία και μην την κόβετε για να αλλάξετε το μήκος της.

ΑΝΕΠΙΘΥΜΗΤΕΣ ΑΝΤΙΔΡΑΣΕΙΣ

- Οι δυνητικές ανεπιθύμητες αντιδράσεις είναι εκείνες που σχετίζονται τυπικά με τα χειρουργικώς εμφυτεύσιμα υλικά, στις οποίες συγκαταλέγεται η εμφάνιση πιθανότητας λοίμωξης, η φλεγμονή, ο σχηματισμός συμφύσεων, ο σχηματισμός συριγγίων, η διάβρωση, η εξώθηση και η δημιουργία συλών που έχουν ως αποτέλεσμα τη συστολή του εμφυτεύματος.
- Κατά τη διέλευση του οδηγού GYNECARE ενδέχεται να προκύψει διάτρηση ή ρήξη αγγείων και νεύρων, καθώς και της ουροδόχου κύστης, της ουρήθρας ή του εντέρου, οι οποίες πιθανόν να απαιτήσουν χειρουργική αποκατάσταση.

ΣΤΕΙΡΟΤΗΤΑ

Τα συστήματα αποκατάστασης πυελικού εδάφους GYNECARE PROLIFT αποστειρώνονται με αιθυλενοξείδιο. ΜΗΝ ΤΑ ΕΠΑΝΑΠΟΣΤΕΙΡΩΝΕΤΕ.
ΜΗΝ ΤΑ ΕΠΑΝΑΧΡΗΣΙΜΟΠΟΙΕΙΤΕ. Μην τα χρησιμοποιείτε εάν η συσκευασία έχει ανοιχτεί ή έχει υποστεί ζημιά. Απορρίψτε όλες τις συσκευές που ανοίχθηκαν αλλά δεν χρησιμοποιήθηκαν.

ΑΠΟΡΡΙΨΗ

Απορρίψτε τις συσκευές και τη συσκευασία τους σύμφωνα με την πολιτική και τις διαδικασίες απόρριψης βιολογικά επικίνδυνων υλικών και αποβλήτων του ιδρύματός σας.

ΦΥΛΑΞΗ

Συνιστώμενες συνθήκες φύλαξης: ελεγχόμενη θερμοκρασία και σχετική υγρασία δωματίου (περίπου 25 °C, 60 % σχετική υγρασία), μακριά από υγρασία και άμεσες πηγές θερμότητας. Μην τα χρησιμοποιείτε μετά από την παρέλευση της ημερομηνίας λήξης.

Σύμβολα που χρησιμοποιούνται στις ετικέτες

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EXHIBIT

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Gynecare

PROLIFT+M™

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

جهاز إصلاح قاع الحوض بالكامل
جهاز إصلاح الجزء الأمامي من قاع الحوض
جهاز إصلاح الجزء الخلفي من قاع الحوض

Сістэма поўнай рэканструкцыі лагвовага дна
Сістэма рэканструкцыі пярэдняга абсягу лагвовага дна
Сістэма рэканструкцыі задняга абсягу лагвовага дна

Система за цялостна реконструкция на тазовото дъно
Система за реконструкция на предната част на тазовото дъно
Система за реконструкция на задната част на тазовото дъно

Systém pro celkovou rekonstrukci pánevního dna
Systém pro rekonstrukci přední části pánevního dna
Systém pro rekonstrukci zadní části pánevního dna

Totalt reparationssystem til bækkenbunden
Reparationssystem til anteriore bækkenbund
Reparationssystem til posteriore bækkenbund

Bekkenbodemreparatiesysteem totaal
Bekkenbodemreparatiesysteem anterieur
Bekkenbodemreparatiesysteem posterieur

Vaagnapõhja rekonstruktsiooni täissüsteem
Vaagnapõhja eesosa rekonstruktsiooni süsteem
Vaagnapõhja tagaosa rekonstruktsiooni süsteem

Totaalinen lantionpohjan korjausjärjestelmä
Anteriorinen lantionpohjan korjausjärjestelmä
Posteriorinen lantionpohjan korjausjärjestelmä

Système de reconstruction complète du plancher pelvien
Système de reconstruction antérieure du plancher pelvien
Système de reconstruction postérieure du plancher pelvien

Totalprolaps-Beckenboden-Rekonstruktionssystem
Anteriores Beckenboden-Rekonstruktionssystem
Posteriores Beckenboden-Rekonstruktionssystem

Σύστημα ολικής αποκατάστασης πυελικού εδάφους
Σύστημα αποκατάστασης πρόσθιου πυελικού εδάφους
Σύστημα αποκατάστασης οπίσθιου πυελικού εδάφους

Teljes medencefenék-rekonstrukciós rendszer
Mellső medencefenék-rekonstrukciós rendszer
Hátsó medencefenék-rekonstrukciós rendszer

Sistema di riparazione totale del pavimento pelvico
Sistema di riparazione anteriore del pavimento pelvico
Sistema di riparazione posteriore del pavimento pelvico

Жамбас түбінің толық қалпына келтіру жүйесі
Алдыңғы жамбас түбін қалпына келтіру жүйесі
Артқы жамбас түбін қалпына келтіру жүйесі

Starpenes kopējās rekonstrukcijas sistēma
Starpenes priekšējā laukuma rekonstrukcijas sistēma
Starpenes aizmugurējā laukuma rekonstrukcijas sistēma

Bendra dubens dugno chirurginio gydymo sistema
Priekinio priėjimo dubens dugno chirurginio gydymo sistema
Užpakalinio priėjimo dubens dugno chirurginio gydymo sistema

System for fullstendig reparasjon av bekkenbunnen
Reparasjonssystem for fremre bekkenbunn
Reparasjonssystem for bakre bekkenbunn

System pełny naprawy dna miednicy
System przedni naprawy dna miednicy
System tylny naprawy dna miednicy

Sistema de reparação do pavimento pélvico total
Sistema de reparação do pavimento pélvico anterior
Sistema de reparação do pavimento pélvico posterior

Sistem de reparație totală a planșeului pelvin
Sistem de reparație anterioară a planșeului pelvin
Sistem de reparație posterioară a planșeului pelvin

Система полной реконструкции тазового дна
Система реконструкции переднего отдела тазового дна
Система реконструкции заднего отдела тазового дна

Systém na rekonštrukciu celého panvového dna
Systém na rekonštrukciu prednej časti panvového dna
Systém na rekonštrukciu zadnej časti panvového dna

Sistema de reparación del suelo pélvico total
Sistema de reparación del suelo pélvico anterior
Sistema de reparación del suelo pélvico posterior

System för total reparation av bäckenbotten
System för reparation av främre delen av bäckenbotten
System för reparation av bakre delen av bäckenbotten

Total pelvik taban onarım sistemi
Ön pelvik taban onarım sistemi
Arka pelvik taban onarım sistemi

Система повної реконструкції тазового дна
Система реконструкції переднього відділу тазового дна
Система реконструкції заднього відділу тазового дна

Manufactured for:
ETHICON Women's Health & Urology
A division of ETHICON, INC.
a Johnson&Johnson company
Somerville, New Jersey 08876-0151

EC
Legal Manufacturer
ETHICON Sàrl
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CH-2000 Neuchâtel
Switzerland

P19074/J

Gynecare

PROLIFT+M™

ENGLISH

Total Pelvic Floor Repair System
Anterior Pelvic Floor Repair System
Posterior Pelvic Floor Repair System

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the devices and lead to injury.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Training on the use of the GYNECARE PROLIFT+M™ Pelvic Floor Repair Systems is recommended and available and is similar to the training for the procedure using the GYNECARE PROLIFT™ Pelvic Floor Repair System. Contact your company sales representative to arrange for this training. Physicians should have experience in management of complications resulting from procedures using surgical mesh.

Refer to the recommended surgical technique guide for the GYNECARE PROLIFT™ Pelvic Floor Repair Systems for further information on the pelvic floor repair procedure. Contact your company sales representative to obtain this surgical technique guide.

The safety and effectiveness of the GYNECARE PROLIFT+M™ Systems compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials. In the United States, substantial equivalence of the GYNECARE PROLIFT+M™ Systems to synthetic mesh with the same indication has been demonstrated through benchtop and cadaveric testing. Information on the clinical performance of mesh for pelvic floor repair is available in published literature. Contact your company sales representative for assistance.

INDICATIONS

The GYNECARE PROLIFT+M™ Total, Anterior, and Posterior Pelvic Floor Repair Systems, through placement of GYNECARE GYNEMESH M™ Partially Absorbable Mesh, are indicated for tissue reinforcement and long lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

CONTRAINDICATIONS

- **GYNECARE GYNEMESH M™ Mesh should not be used in infants, children, pregnant women, or women planning future pregnancies, as the mesh will not stretch significantly as the patient grows.**
- **GYNECARE GYNEMESH M™ Mesh must always be separated from the abdominal cavity by peritoneum.**
- **GYNECARE GYNEMESH M™ Mesh must not be used following planned intra-operative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection that may require removal of the mesh.**
- **The GYNECARE PROLIFT+M™ Systems should not be used in the presence of active or latent infections or cancers of the vagina, cervix, or uterus.**

WARNINGS

- **Patients on anticoagulation agents undergoing surgery using the GYNECARE PROLIFT+M™ System must have their anticoagulation therapy carefully managed.**
- **Do not remove the GYNECARE PROLIFT™ Cannulas from the patient until the mesh implant has been properly positioned.**
- **A digital rectal exam should be performed to detect possible rectal perforation.**
- **Cystoscopy may be performed to confirm bladder integrity or detect possible bladder or ureteral perforation.**
- **Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.**
- **Use the GYNECARE PROLIFT+M™ Systems with care, and with attention to patient anatomy and to proper dissection technique, to avoid damage to vessels, nerves, bladder, bowel, and vaginal wall perforation. Correct use of the GYNECARE PROLIFT+M™ Systems components will minimize risks.**
- **Transient leg pain may occur and can usually be managed with mild analgesics.**

PRECAUTIONS

- **Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing the GYNECARE PROLIFT+M™ Systems.**
- **Avoid placing excessive tension on the mesh implant during placement.**
- **Do not manipulate the GYNECARE PROLIFT™ Retrieval Device with sharp instruments or cut it to alter its length.**
- **Do not affix the GYNECARE GYNEMESH M™ Mesh Implant with any staples, clips, or clamps as mechanical damage to the mesh may occur.**
- **This product should only be used under the prescription of a physician.**
- **In patients with compromised immune systems or other conditions that would compromise healing the risks and benefits should be carefully weighed.**
- **Vaginal or urinary tract infection should be treated and alleviated prior to implantation.**
- **Acceptable surgical practice should be followed for the GYNECARE PROLIFT+M™ Systems as well as for the management of infected or contaminated wounds. If the Mesh Implant is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal.**
- **Prolapse repair may unmask pre-existing incontinence conditions.**
- **Prophylactic antibiotics can be administered according to the surgeon's usual practice.**
- **The use of this product with tissue adhesives is not recommended, as data are not currently available.**

ADVERSE REACTIONS

- **Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, including hematoma, urinary incontinence, urinary retention/obstruction, ureter obstruction, voiding dysfunction, pain, infection potentiation, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring, and mesh exposure, erosion, or extrusion.**
- **Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT™ Guide passage and may require surgical repair.**
- **Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse. These may resolve with time.**
- **Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.**

CLINICAL PERFORMANCE

Randomized, controlled clinical evaluations of the GYNECARE PROLIFT™ System are underway, but at this time preliminary data are available from two early observational studies of transvaginal mesh that were initiated in 2004. These observational studies evaluated a pre-cut surgical mesh made of the same non-absorbable polypropylene as the mesh used in the GYNECARE PROLIFT™ System.

DESCRIPTION

The GYNECARE PROLIFT+M™ Total, Anterior, and Posterior Pelvic Floor Repair Systems consist of pre-cut GYNECARE GYNEMESH M™ Mesh implants and a set of instruments to facilitate mesh implant placement. The mesh implant is provided separate from the instruments, in a foil pouch with a paper folder designed for easy access of the mesh implant. The mesh implant may be trimmed while held in the paper folder. The following table summarizes the instruments included with each system:

REPAIR SYSTEM	COMPONENTS			
	Mesh Implant	Guide	Retrieval Devices	Cannulas
Total	1 Total	1	6	6
Anterior	1 Anterior	1	4	4
Posterior	1 Posterior	1	2	2

Table 1 – Components of the GYNECARE PROLIFT+M™ Pelvic Floor Repair Systems

GYNECARE GYNEMESH M™

GYNECARE GYNEMESH M™ Mesh is manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber. The polymer of the undyed and dyed polypropylene fiber (phthalocyanineblue, Color Index No.: 74160) is identical to the material used for dyed / undyed PROLENE® Polypropylene Suture material. Blue PROLENE® Suture monofilaments have been incorporated to produce contrast striping in the mesh. Poliglecaprone-25 fiber consists of a copolymer containing glycolide and ε-caprolactone; this copolymer is identical to the material used for MONOCRYL® (Poliglecaprone 25) Suture. The absorbable poliglecaprone part of the mesh aids handling, making intraoperative manipulation and positioning of the mesh easier. After absorption of the poliglecaprone-25 component, only the polypropylene mesh remains, which has burst strength of approximately 621 kPa (90 psi).

Total Implant

The Total Implant is constructed from GYNECARE GYNEMESH M™ Mesh and is shaped for performing a total vaginal repair. The Total Implant has six straps: four for securing the anterior portion of the implant via a transobturator approach and two for securing the posterior portion of the implant in the sacrospinous ligament via a transgluteal approach. Alternatively, the two posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The proximal and distal anterior straps have squared and triangular ends, respectively, while the posterior straps have rounded ends *(see Figure 1A)*.

Anterior Implant

The Anterior Implant is constructed from GYNECARE GYNEMESH M™ Mesh and is shaped for repair of anterior vaginal defects. The Anterior Implant has four straps that are secured via a transobturator approach. The proximal and distal anterior straps have squared and triangular ends, respectively *(see Figure 1B)*.

Posterior Implant

The Posterior Implant is constructed from GYNECARE GYNEMESH M™ Mesh and is shaped for repair of posterior and/or apical vaginal vault defects. The Posterior Implant has two straps that are secured in the sacrospinous ligament via a transgluteal approach. Alternatively, the two posterior straps may be cut to reduce their length and secured in the sacrospinous ligament via a vaginal approach. The posterior straps have rounded ends *(see Figure 1C)*.

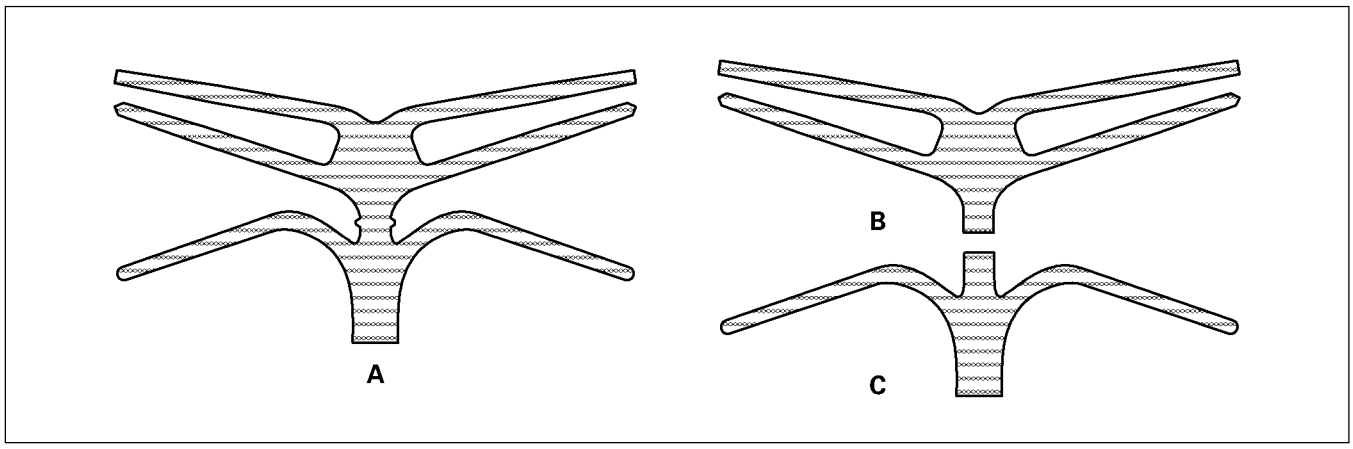


Figure 1 – Mesh Implants (Total, Anterior, Posterior)

GYNECARE PROLIFT™ Guide

The GYNECARE PROLIFT™ Guide is a single-patient-use instrument designed to create tissue paths to allow placement of the Total, Anterior, and Posterior Implants and to facilitate placement of the GYNECARE PROLIFT™ Cannula. Its length and curvature are specifically designed to create proper placement paths for all mesh implant straps. The GYNECARE PROLIFT™ Guide is suitable for use on both sides of the patient *(see Figure 2)*.

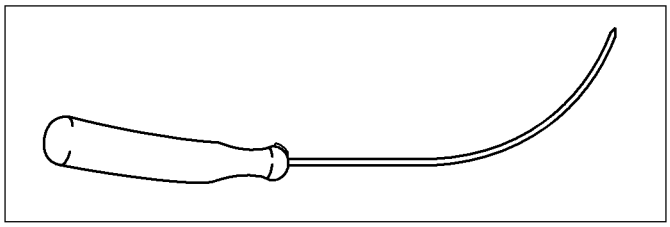


Figure 2 – GYNECARE PROLIFT™ Guide

GYNECARE PROLIFT™ Cannula
The GYNECARE PROLIFT™ Cannula is a single-patient-use instrument used in conjunction with the GYNECARE PROLIFT™ Guide to facilitate passage of the implant straps while protecting the surrounding tissue. Each GYNECARE PROLIFT™ Cannula is placed over the GYNECARE PROLIFT™ Guide prior to passage and remains in place after the GYNECARE PROLIFT™ Guide is withdrawn *(see Figure 3).*

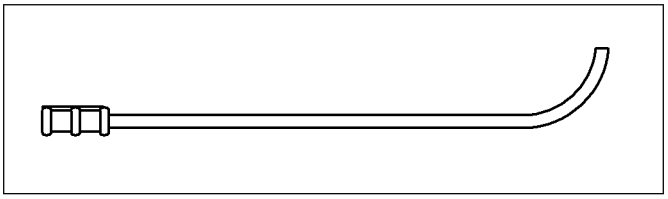


Figure 3 – GYNECARE PROLIFT™ Cannula

GYNECARE PROLIFT™ Retrieval Device
The GYNECARE PROLIFT™ Retrieval Device is a single-patient-use instrument designed to facilitate placement of the mesh implant straps. The GYNECARE PROLIFT™ Retrieval Device is passed through the previously positioned GYNECARE PROLIFT™ Cannula until its distal end is retrieved through the vaginal dissection. The distal end of the GYNECARE PROLIFT™ Retrieval Device has a loop to securely capture the mesh implant strap as the strap is drawn out through the GYNECARE PROLIFT™ Cannula *(see Figure 4).*

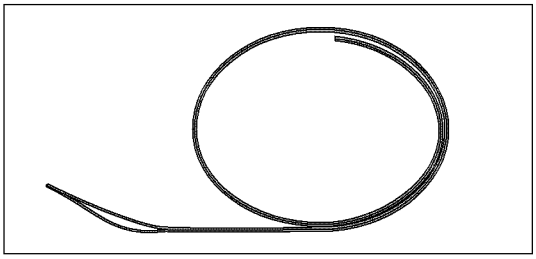


Figure 4 – GYNECARE PROLIFT™ Retrieval Device

PERFORMANCE
Animal studies show that implantation of GYNECARE GYNEMESH M™ Mesh elicits a minimum to mild inflammatory reaction which is followed by collagen tissue ingrowth through the mesh, thus incorporating the mesh into adjacent tissue. The mesh remains soft and pliable, and normal wound healing is not noticeably impaired.

In GYNECARE GYNEMESH M™ Mesh implanted subcutaneously in rats, the poliglecaprone-25 copolymer is essentially absorbed within 84 days after implantation. The polypropylene portion is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes. In an animal model, excessive connective tissue deposition and deleterious scar plate formation did not occur. The mesh construction permits trimming of the implant without unraveling.

STERILITY
The GYNECARE PROLIFT+M™ Systems are sterilized by ethylene oxide. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

DISPOSAL
Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

STORAGE
Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), away from moisture and direct heat. Do not use after expiry date.

INSTRUCTIONS FOR USE
NOTE: All figures below are not intended to provide any clinical teaching and only demonstrate the general use of each device.

Placement of the GYNECARE PROLIFT™ Cannula onto the GYNECARE PROLIFT™ Guide (See Figures 5A and 5B)

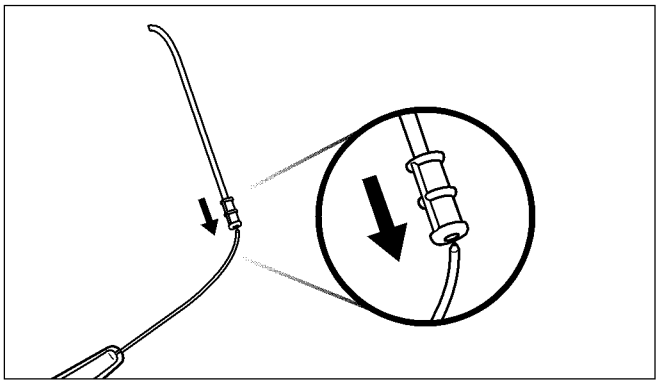


Figure 5A

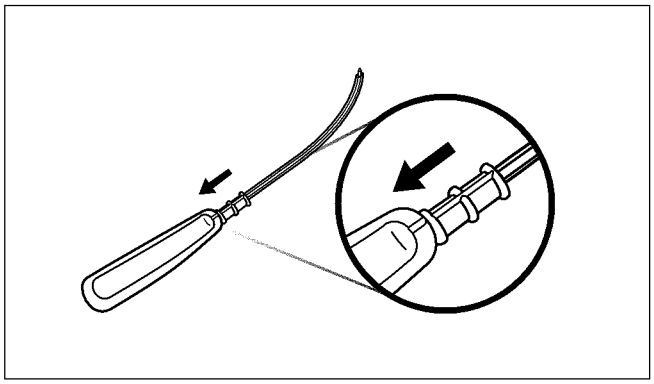


Figure 5B

IMPORTANT: Ensure proper alignment of GYNECARE PROLIFT™ Cannula and GYNECARE PROLIFT™ Guide upon assembly as demonstrated in Figure 5B.

Placement of the GYNECARE PROLIFT™ Cannula into the Patient (See Figures 6A, 6B, and 6C)

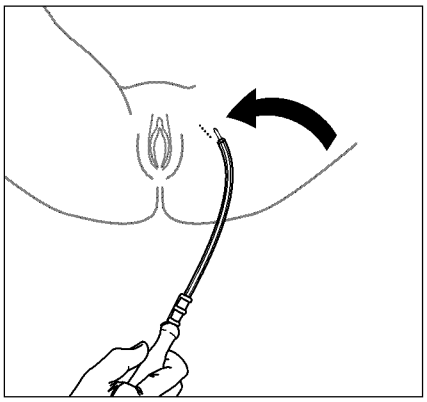


Figure 6A

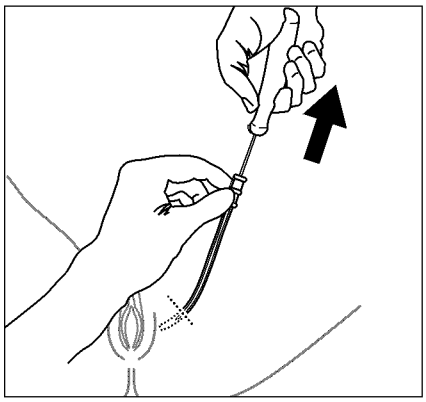


Figure 6B

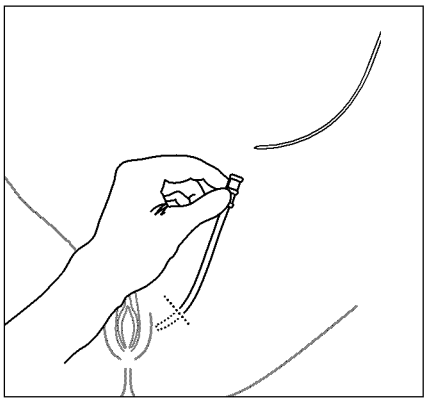


Figure 6C

Insertion and Passage of the GYNECARE PROLIFT™ Retrieval Device into the GYNECARE PROLIFT™ Cannula (See Figures 7A and 7B)

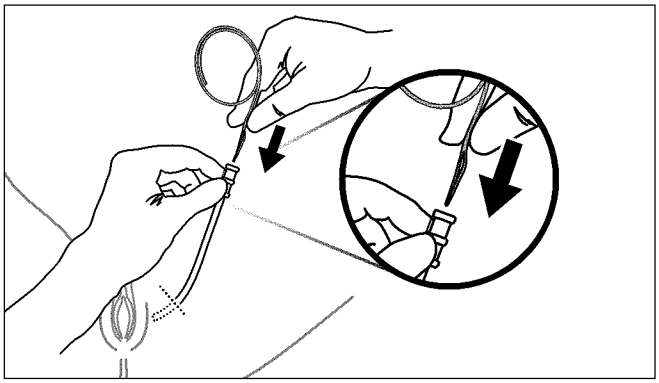


Figure 7A

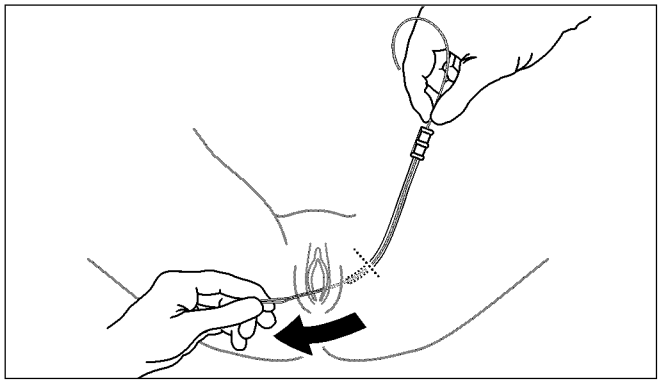


Figure 7B

IMPORTANT: **All provided GYNECARE PROLIFT™ Cannulas and GYNECARE PROLIFT™ Retrieval Devices should be placed prior to mesh implant installation.**

Capture of a Mesh Implant Strap with GYNECARE PROLIFT™ Retrieval Device (See Figures 8A, 8B, 8C)

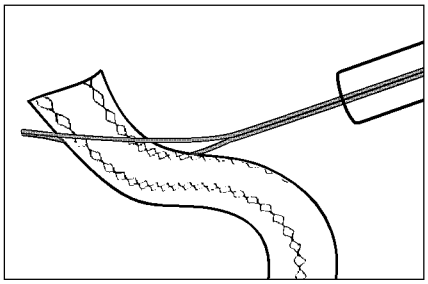


Figure 8A

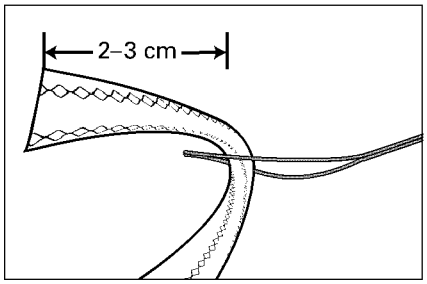


Figure 8B

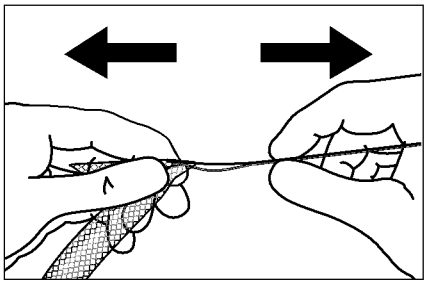


Figure 8C

Passage of a Mesh Implant Strap through the GYNECARE PROLIFT™ Cannula (See Figures 9A, 9B, 9C)

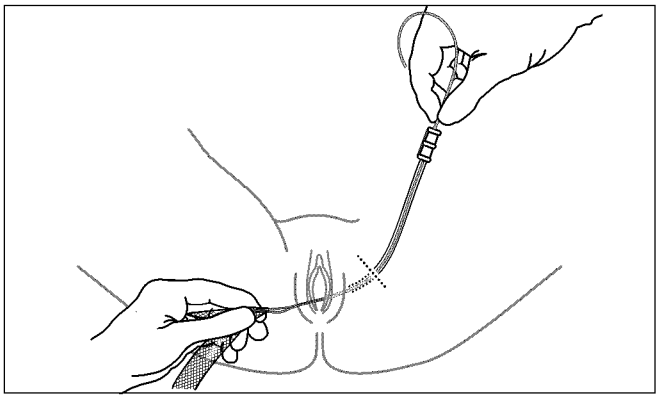


Figure 9A

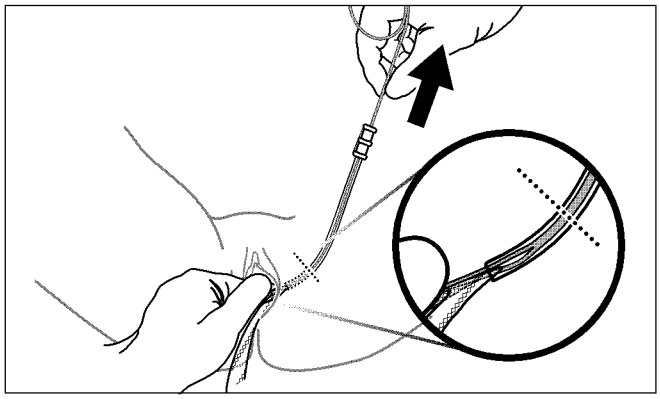


Figure 9B

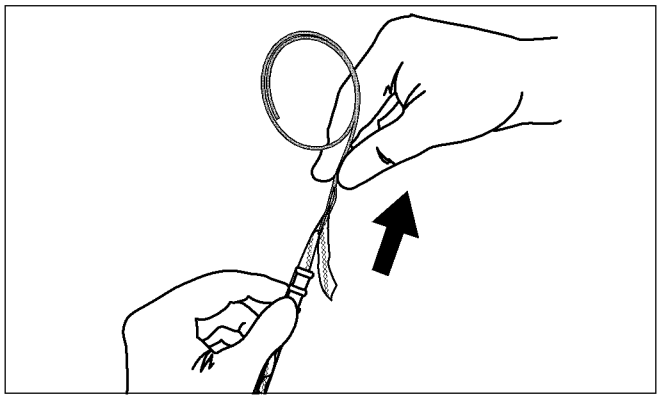
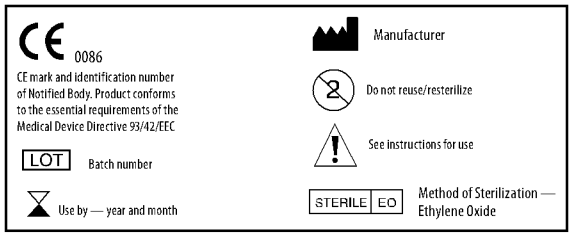


Figure 9C

IMPORTANT: Do not remove the GYNECARE PROLIFT™ Cannulas from the patient until the mesh implant has been properly positioned.
In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 1 cm (3/8") from the edge of the mesh.

HOW SUPPLIED
GYNECARE PROLIFT+M™ Systems are supplied in three different kits for Anterior, Posterior, or Total (Anterior + Posterior) pelvic floor repair. The GYNECARE GYNEMESH M™ Mesh implant is provided pre-shaped and sterile within a foil pouch. The GYNECARE PROLIFT™ Guide, the GYNECARE PROLIFT™ Retrieval Devices, and the GYNECARE PROLIFT™ Cannulas are provided sterile in a thermoformed tray, separate from the GYNECARE GYNEMESH M™ Mesh implant.

Symbols Used on Labeling



EXHIBIT

“C”

GYNECARE TVT*

Obturator System

Tension-free Support for Incontinence

GYNECARE TVT* obturatorsystem
Spændingsfri støtte til inkontinens

GYNECARE TVT* obturatorsysteem
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT* -obturaattorijärjestelmä
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT*
Dispositif sans tension contre les incontinences

GYNECARE TVT* Obturatorsystem
Spannungsfreie Unterstützung bei Inkontinenz

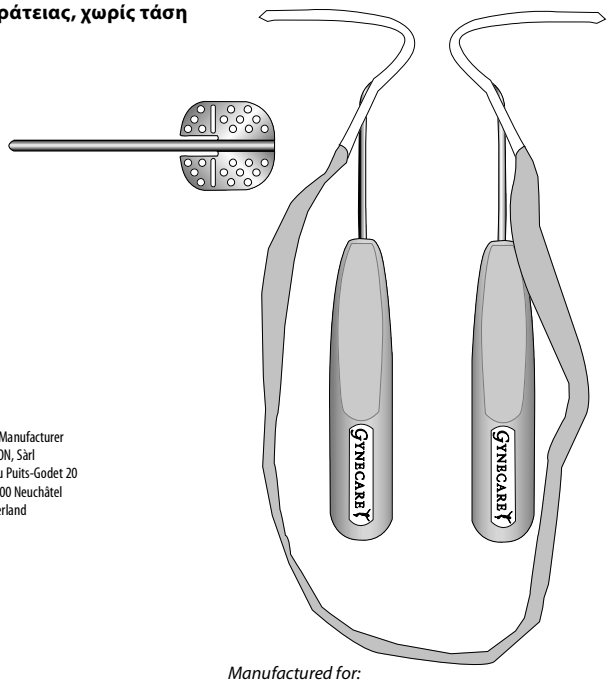
Sistema otturatorio GYNECARE TVT*
Dispositivo tension-free per l'incontinenza

Sistema obturador GYNECARE TVT*
Apoio sem tensão para incontinência

Sistema obturador GYNECARE TVT*
Protector sin tensión para la incontinencia

GYNECARE TVT* obturatoriabandsystem
Tensionsfritt stöd för behandling av inkontinens

Σύστημα επιπωματικού GYNECARE TVT*
Σύστημα υποστήριξης για την αντιμετώπιση της ακράτειας, χωρίς τάση



EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits-Godet 20
CH-2000 Neuchâtel
Switzerland

Manufactured for:

GYNECARE WORLDWIDE
A division of ETHICON, INC.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland

P18070/D

ENGLISH

GYNECARE TVT* Obturator System
Tension-free Support for Incontinence

GYNECARE TVT Obturator Device, Sterile Single Use

GYNECARE TVT Obturator Helical Passers, Sterile Single Use

GYNECARE TVT Obturator Atraumatic Winged Guide, Sterile Single Use

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT* Obturator System, including the GYNECARE TVT Obturator device, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT Obturator System is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT Obturator device

The GYNECARE TVT Obturator device is a sterile, single patient use device, consisting of one piece of undyed or blue (Phtalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT Helical Passers

The GYNECARE TVT Helical Passers are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT Obturator device. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT Obturator device. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT Atraumatic Winged Guide

The GYNECARE TVT Atraumatic Winged Guide is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT Helical Passers through the dissection tract.

INDICATIONS

The GYNECARE TVT Obturator device is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. If desired, retract the labia to provide additional exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. *(See Figure 1)*

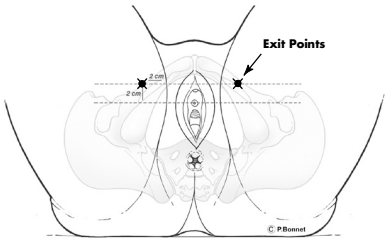


FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

   (Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

   After initiating sharp dissection, continue by using a "push-spread technique", to perform blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented on the horizontal plane *(See Figure 2)*. Continue dissection towards the junction between the body of the pubic bones and the inferior pubic ramus. *(See Figure 2)*

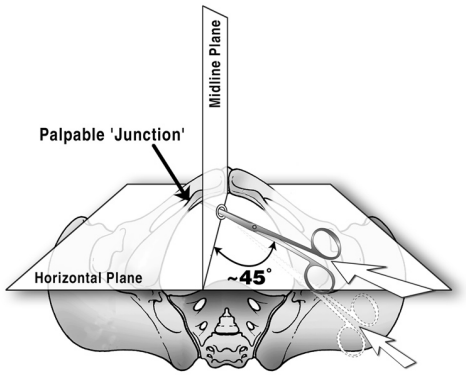


FIG. 2

   When the junction between the body of the pubic bones and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the internal package workstation from the external package. Then remove the GYNECARE TVT Winged Guide from the package workstation. *(See Figure 3)*

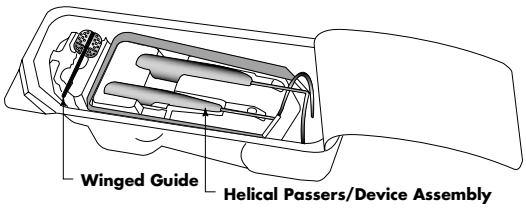


FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

   If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

   (Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT Obturator device assembly from the sterile pack *(See Figure 3 for components)*.

(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

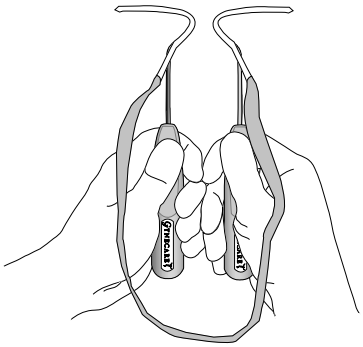


FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assure that the tape is not twisted.

11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. *(See Figure 5)*

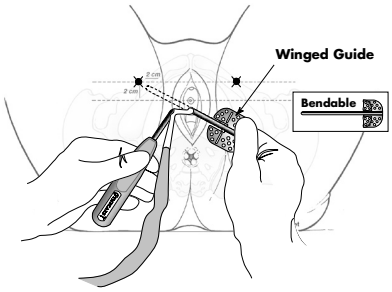


FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

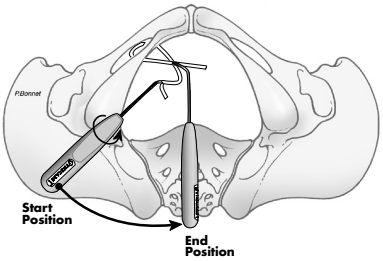


FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer as you simultaneously move towards the midline until the handle is vertical to the floor. *(See Figure 6)* ***(Note: Never allow the handle to be oriented horizontal to the floor.)***

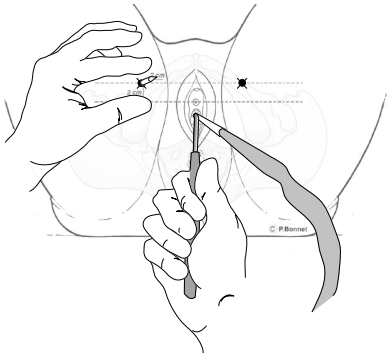


FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points *(See Figure 7)*. However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp the pointed tip of the plastic tube with a clamp and, while stabilizing the tube near the urethra with the thumb, remove the Helical Passer by a reverse rotation of the handle. *(See Figure 8)*

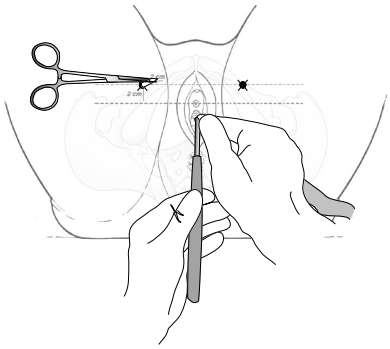


FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. *(See Figure 9)*

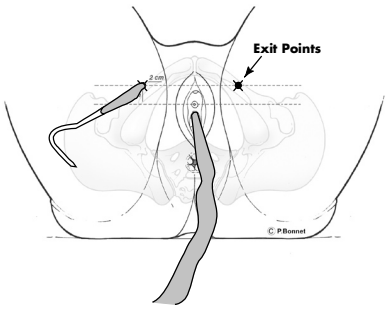


FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. *(See Figure 10)*

(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

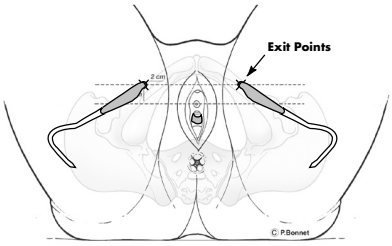


FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the midurethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. *(See Figure 11)*

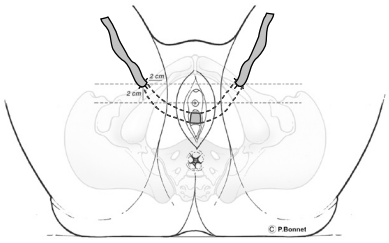


FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. Place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths, or use other suitable means during sheath removal, to avoid positioning the tape with tension.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.

19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT Obturator procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT Obturator procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT Obturator procedure before employing the GYNECARE TVT Obturator device.
- Acceptable surgical practice should be followed for the GYNECARE TVT Obturator procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT Obturator procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT Obturator System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT Obturator System, in case of pregnancy delivery via cesarean section should be considered.

- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT Obturator System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT Obturator device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

The GYNECARE TVT Obturator System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

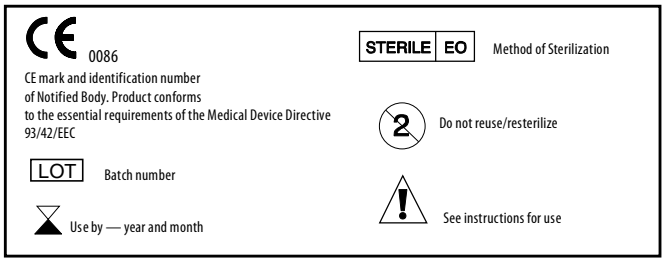
STORAGE

Recommended storage conditions for the GYNECARE TVT Obturator System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

*Trademark

SYMBOLS USED ON LABELING



EXHIBIT

“D”

Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse (Review)

Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J

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[Intervention Review]

Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse

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ABSTRACT

Background

A wide variety of grafts have been introduced with the aim of improving the outcomes of traditional native tissue repair (colporrhaphy) for vaginal prolapse.

Objectives

To determine the safety and effectiveness of transvaginal mesh or biological grafts compared to native tissue repair for vaginal prolapse.

Search methods

We searched the Cochrane Incontinence Group Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, ongoing trials registers, and handsearching of journals and conference proceedings *(6* July 2015*).* We also contacted researchers in the field.

Selection criteria

Randomised controlled trials (RCTs) comparing different types of vaginal repair (mesh, biological graft, or native tissue).

Data collection and analysis

Two review authors independently selected trials, assessed risk of bias, and extracted data. The primary outcomes were awareness of prolapse, repeat surgery, and recurrent prolapse on examination.

Main results

We included 37 RCTs (4023 women). The quality of the evidence ranged from very low to moderate. The main limitations were poor reporting of study methods, inconsistency, and imprecision.

Permanent mesh versus native tissue repair

- when these products are used correctly they can help alleviate the very distressing symptoms of stress urinary incontinence and pelvic organ prolapse, and as such the benefits still outweigh the risks.

Our review suggests that while permanent transvaginal mesh is associated with a greater reduction in prolapse on examination, awareness of prolapse and reoperation for prolapse than native tissue repairs, it is associated with increased morbidity, including a higher rate of bladder injury, de novo stress urinary incontinence, and reoperation rates for prolapse, stress urinary incontinence, and/or mesh exposure. The rate of mesh exposure was 12%, and surgery for mesh exposure was required in 8%, accounting for most of the reoperations for mesh complications. We conclude, in contrast to the MHRA 2014 report, that while there may be individual cases of anterior compartment prolapse where mesh utilisation may be warranted, it cannot be considered a first-line treatment option for pelvic organ prolapse, due to the associated morbidity.

Furthermore, and in contrast to the MHRA 2014 report, we have highlighted that most of data informing our report was derived from transvaginal mesh products that were voluntarily removed from the market in 2012, and that transvaginal mesh products currently available for use have not been evaluated by RCTs. We believe it is prudent that until such data become available, the currently available transvaginal mesh products should be utilised in a clinical setting under the discretion of the local ethics committee.

A recent Cochrane systematic review (Ford 2015) assessed mid-urethral sling operations for the treatment of women with stress urinary incontinence. It included comparisons of different surgical routes, different types of synthetic tape and types of tape insertion. The review authors concluded that the surgery has a good safety profile and is highly effective in the short and medium term. This review has limited applicability to the current review, as it included women with or without pelvic prolapse; most trials did not report whether prolapse was present. Moreover none of the trials directly compared traditional anterior repair (with native tissue) to mid-urethral synthetic sling.

AUTHORS' CONCLUSIONS

Implications for practice

While transvaginal permanent mesh is associated with lower rates of awareness of prolapse and prolapse on examination than native tissue repair, permanent mesh is also associated with increased morbidity, including a higher rate of reoperation for prolapse, stress urinary incontinence, or mesh exposure and higher rates of bladder injury at surgery and de novo stress urinary incontinence. The risk-benefit profile means that transvaginal mesh has limited utility in primary surgery. While it is possible that the benefits may outweigh the risks in women with higher risk of recurrence, there is currently no evidence to support this position.

Limited evidence suggests that absorbable mesh may reduce the risk of recurrent prolapse on examination compared to native tissue repair, but there was insufficient evidence on absorbable mesh for us to draw any conclusions for other outcomes.

In 2011, many of the transvaginal permanent meshes evaluated in this review were voluntarily withdrawn from the market. To date, the newer, lightweight transvaginal permanent meshes that remain of the market have not been evaluated within a RCT. Until such data become available, these newer transvaginal meshes should be utilised under the discretion of the ethics committee.

Implications for research

In the short term, urgent evaluation of newer, lighter transvaginal mesh products that remain on the market is required. Unfortunately, at least two trials have received ethical committee approval comparing the new lightweight mesh with either sacral colpopexy or transanal repair (NCT01097200; NCT01497171), but have been terminated due to difficulty in recruiting or lack of funding. These products should also be compared to native tissue repairs and sacral colpopexy. In the medium to long term, the development of newer, self rejuvenating products through tissue engineering and bio-design should be funded, and the efficacy, safety, and cost of the interventions assessed. A cost-benefit analysis of transvaginal mesh is needed, and the long-term outcomes of meshes already evaluated should also be undertaken.

ACKNOWLEDGEMENTS

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